**Appendix figure 1:** Individual study risk of CRI and overall meta-analysis (fixed-effects) of the risk of CRI in pregnancy cohorts of women susceptible to rubella and vaccinated against rubella peri-conceptually: data from Reyna[[1](#_ENREF_1)] and Lina[[2](#_ENREF_2)] omitted.

Overall (I-squared = 0.0%, p = 0.468)

Tookey, P (2001)

Hamkar (2006)

ACIP ’79-‘88 (1989)

Castillo- Solorzano

\* (2011)

ID

Enders (2005)

ACIP ’71-‘79 (1983)

Study

Enders (1985)

3.41 (2.64, 4.18)

16.00 (4.54, 36.08)

8.57 (1.80, 23.06)

1.95 (0.40, 5.59)

3.54 (2.77, 4.45)

Percent (95% CI)

7.69 (0.19, 36.03)

4.92 (1.03, 13.71)

2.11 (0.26, 7.40)

100.00

0.24

0.53

8.83

84.10

Weight

0.18

1.48

%

4.65

3.41 (2.64, 4.18)

16.00 (4.54, 36.08)

8.57 (1.80, 23.06)

1.95 (0.40, 5.59)

3.54 (2.77, 4.45)

Percent (95% CI)

7.69 (0.19, 36.03)

4.92 (1.03, 13.71)

2.11 (0.26, 7.40)

100.00

0.24

0.53

8.83

84.10

Weight

0.18

1.48

%

4.65

0

0

10

20

30

40

50

**Appendix figure 2** Individual study risk of CRI and overall meta-analysis (fixed-effects) of the risk of CRI in pregnancy cohorts of women susceptible to rubella and vaccinated against rubella peri-conceptually: data from studies where other vaccines apart from RA27/3 was used (ie ACIP 1971-1979, Enders 1985 and Tookey 2001 omitted)

Overall (I-squared = 86.3%, p = 0.000)

Study

Castillo- Solorzano

\* (2011)

Hamkar (2006)

ACIP ’79-‘88 (1989)

ID

Enders (2005)

Lina (2008)

Reyna (2011)

1.69 (1.15, 2.24)

3.54 (2.77, 4.45)

8.57 (1.80, 23.06)

1.95 (0.40, 5.59)

Percent (95% CI)

7.69 (0.19, 36.03)

0.38 (0.01, 2.11)

0.00 (0.00, 2.10)

100.00

%

41.75

0.26

4.38

Weight

0.09

26.75

26.77

1.69 (1.15, 2.24)

3.54 (2.77, 4.45)

8.57 (1.80, 23.06)

1.95 (0.40, 5.59)

Percent (95% CI)

7.69 (0.19, 36.03)

0.38 (0.01, 2.11)

0.00 (0.00, 2.10)

100.00

%

41.75

0.26

4.38

Weight

0.09

26.75

26.77

0

0

10

20

30

40

50

**Appendix Table 1. Baseline characteristics of vaccinated pregnancy cohorts without information on outcomes stratified by susceptibility of mother to rubella**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author, year** | **Location, recruitment year(s), publication type** | **Vaccine**  **R/MR/MMR, rubella strain, type of programme and target age range** | **N(%) susceptible,**  **N(%) immune,**  **N(%) unknown** | **N (% ) vaccinated by timing of vaccination** | **N followed up for (CRS/CRI)**  **By timing of vaccination** | **Type and N outcomes** | **Virological test for vaccine strain done?** | **Comments** |
| **Chin, J., 1971[**[**3**](#_ENREF_3)**]** | Los Angeles area USA,  1969- 1970, brief report | NK | 5(29.4%) susceptible | Time of immunization ranged from 84 days before to 88 days after the last menstrual period  5 women vaccinated 12-4 weeks before LMP  4 women vaccinated < 4 weeks before LMP  8 women vaccinated up to 13 weeks after LMP | 4 apparently normal infants by time of writing | 6 therapeutic (concern about possible teratogenic effect of the vaccine) abortions, 1 spontaneous abortion, 4 apparently normal infants, 6 continuing pregnancies at the time of writing | Virological studies on the products of conception from some of the therapeutic abortions and from the apparently normal infants in progress, but results not available at the time of writing |  |
| **Larson, H. E.,**  **1971**  **[**[**4**](#_ENREF_4)**]** | Laboratory of viral immunology, Maryland, USA,  journal article | HPV-77(5) (3 women)  HPV-77 (12) (1 woman)  Unknown ( 5 women)  Inadvertent vaccination during pregnancy:  7 women vaccinated by private physician, 2 by public vaccination program directed at prepubertal children | 9 women- immune status unknown | 8 women were vaccinated 7-81 days after LMP  1 woman was vaccinated on the day of her LMP | 8 induced abortion | Virus was recovered from the products of conception of 2 women (out of 5 who received HPV-77). 1 had serologic confirmation of infection | yes ‘Unmodified and the attenuated HPV-77 viruses were included in each test. Isolates from the vaccines produced prompt, marked cytopathic effects in “roller-tube “cultures of RK13 monolayers, and induced interferon. These findings were also characteristic of the HPV-77 attenuated virus and were in contrast to the behaviour of unmodified virus in the same test systems.’ P. 872 | 1 pregnancy proceeded to term and despite prematurity, the baby had developed normally and was negative for virus. |
| **Mair, H. J.,**  **1972[**[**5**](#_ENREF_5)**]** | UK,  1970-1972, journal article | Inadvertent vaccination during pregnancy | 6 women  2 mothers susceptible,  4 unknown | 3 (50%) <1 month before LMP, 3 (50%) <1 month after LMP | Until termination of pregnancy (maximum follow up 19 weeks) | 5 therapeutic abortions, 1 spontaneous abortion. Each product of conception examined virologically, with negative results. | NA |  |
| **Allan, B. C., 1973[**[**6**](#_ENREF_6)**]** | Australia,  1973,  journal article | Cendehill ,  Inadvertent vaccination in pregnancy, | 7 (11.1%) susceptible,  58 (89.2%) unknown | 8: > 6 weeks before conception  53: 6 weeks before to 6 weeks after conception,  4: > 6 weeks of gestation | 19 live infants by time of paper | 0 CRS  1 virus isolation from placenta material, but no duplication possible, probably cross-contamination in the lab (susceptible mother)  Examination of infants by paediatricians/specialists not explicitly mentioned | **Unclear** |  |
| **Fleet, W. F., 1974[**[**7**](#_ENREF_7)**]** | Tennesse, USA,  journal article | NK | 1 (5.3%) susceptible,  1 (5.3%) immune,  17 (89.5%) unknown | Weeks before conception:  9-12 = 3(18.7%)  5-8= 3(18.7%)  0-4=4(25%)  After  0-4=3(18.7%)  5-8=1 (6.2%)  9-12= 1(6.2%)  13-24= 1(6.2%) | 10 liveborn children, 9 throat swabs available + 5 urine: no virus isolated in specimen: FU studies on 9 children for 3 to 11 months physical exam normal | 9 abortions, 6 were in those vaccinated within 4 weeks of conception. 1 was a spontaneous abortion and 7 were induced abortions. No virus was isolated in these 8 abortions.  In the 9th, in a mother vaccinated 7 weeks after conception, an “interfering” agent was isolated from the eye suspension of the fetus after an induced abortion. Congenital rubella infection of eye, from a virus-positive vaccine strain  was concluded by the authors. | Yes in eye, based on in- vitro growth characteristics of all cultures | Results of physical examinations, Denver Development Screening Tests and hearing tests were normal in all infants |
| **Marks, J. S.,**  **1981[**[**8**](#_ENREF_8)**]** | Hawaii, journal article | Inadvertent vaccination during pregnancy: 23 vaccinated at public clinics  17 vaccinated by private physicians | 40 women | NK | NK | 28 (70%) elective abortion  1 spontaneous miscarriage  11 delivered normal children | No information |  |
| **Nasiri, R., 2009[**[**9**](#_ENREF_9)**]** | Islamic Republic of Iran, 2003, journal article | MR vaccine,  RA27/3 strain,  Nationwide campaign, 5-25year olds | 60 pregnant women | All women vaccinated in 1-4 week periconceptional period | 60 newborns had physical examined at birth and at 1 month of age by paediatrician. All neonates had umbilical cord blood tested | 0/60 CRS  (None of the neonates had evidence of IUGR, cardiovascular, ophthalmic, CNS, or other organ system anomalies)  0/60 CRI  4/60 preterm | NA (no CRI) | 35 (65%) pregnant women had no history of rubella infection, 7 (11.7%) had previous history of rubella,  14 (23.3%) had no clear history |
| **Ergenoglu A. M.,**  **2012[**[**10**](#_ENREF_10)**],** | Turkey  Began in 2009, journal article | R-VAC, Keymen Pharmaceuticals\*  National campaign targeted at women aged 18-35,  \*Most likely RA27/3 | 62 women  Immune status not known. Serological evaluation of mothers prior to vaccination was not possible, but all mothers IgG(+). | During first trimester of pregnancy or within one month before last menstrual period (application during first trimester) | 17 followed up until end of pregnancy, normal deliveries | IgM and IgG antibodies assessed by rubella ELISA IgM and IgG kits at first visit after vaccination of women and from fetal cord blood at birth . Only 1 woman IgM weakly positive. Rubella-specific IgM antibodies testing of cord blood negative in all cases. None of the neonates had clinical evidence of intrauterine growth restriction or cardiovascular, ophthalmologic, central nervous system or other system abnormalities. All auditory screenings were normal. | NA |  |

**Appendix table 2. Baseline table with study characteristics (Case series, Case studies)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **First Author,year** | **Location** | **Time period of study** | **Vaccine**  **R/MR/MMR, rubella strain** | **N (%) vaccinated by timing of vaccination** | **Length and type of follow up** | **Type and N outcomes** | **Virological test for vaccine strain done?** | **Comments** |
| **Phillips, C. A,1970[**[**11**](#_ENREF_11)**].** | US | 1970 | NK | 1, 3 weeks of gestation in a susceptible woman | Pregnancy terminated at 8 weeks. Tissue specimens obtained at surgery. | 1 case of vaccine induced intrauterine rubella infection | Yes | Interferon assays carried out in cultures were higher than that seen with wild type virus and lower inhibition of in vitro lymphocyte transformation activity than wild type virus both consistent with vaccine virus |
| **Ebbin,A.J. 1972[**[**12**](#_ENREF_12)**]** | US | 1972 | Cendehill | 55 days after LMP | Pregnancy terminated 98 days after vaccination | HI titre 1970 <1/8. After vaccination (82 days) HI titre 1/512. No evidence of congenital abnormality. Virus cultured only from femoral bone marrow, not from other organ systems or placenta | No | Viral culture according to “standard methods” in “RK-13 and BSC-1 cell lines” |
| **Giles P. F. H., 1973[**[**13**](#_ENREF_13)**]** | Australia | 1970-1972 | Cendehill | 1, 3 days after LMP | NK | Baby delivered at 39 weeks gestation with no evidence of congenital abnormality. No CRI at testing 6 weeks after delivery | No | Viral culture done placental material negative |
| **Colombo, M.L., 1976[**[**14**](#_ENREF_14)**]** | Italy | 1973 | NK | 1, >3 months after conception | 13.5 months, active follow up | Baby born with malformations and low birth weight. At 10 months was diagnosed with some clinical features compatible with CRS; deafness, mental retardation as well as thorax and tibial deformity with no movement lower legs. | No | No laboratory tests mentioned |
| **Banatvala, J. E., 1981[**[**15**](#_ENREF_15)**]** | UK | 1980 | RA27/3 | 1, 2 weeks after conception | Pregnancy terminated at week 12 | Products of conception cultured in RK 13 rubella virus antigen detected by indirect immunofluorescence, no rubella specific IgM detected | No | Not stated, presumed not done |
| **Higaki,Y 1989[**[**16**](#_ENREF_16)**]** | Japan | 1987 | Takahashi (The Kitasato Institute) | Within 6 weeks of conception | Followup to 9 months of age | Baby delivered at 41 weeks by caesarean section with no clinical evidence of CRS. HI rubella antibody test <1:8 and IgG and IgM Elisa antibodies negative at 9 months | No | No information of bloods done at birth or if rubella IgM in cord blood tested. |
| **Hofmann, J., 2000[**[**17**](#_ENREF_17)**]** | Germany | 1998-2000 | RA27/3 | 1 case of intrauterine infection, mother vaccinated 3 weeks after conception.  5 other susceptible women mentioned | Virus isolation in week 16. 6 further ultrasounds (until week 36). Physical examinations of infant until 14 months | At week 16 virus isolation and PCR in amniotic fluid and fetal blood was positive for vaccine strain rubella virus.  Healthy baby delivered at 40 weeks , no anomalies in physical examinations, hearing tests inconspicuous. Regular development until 14 months of age. | Yes including PCR tests | 5 other women with live births and no CRI or CRS. No mention of how identified or if reported elsewhere |
| **Sukumaran, L. , 2015[**[**18**](#_ENREF_18)**]** | US, | 2003-2013 | MMR | 131, immune status not known 82 [62.6%] in the first trimester |  | Data mining of spontaneous reports VAERS database. No unusual patterns with regard to pregnancy and pregnancy outcomes | NA | Spontaneous reports from clinicians and public to VAERS database. MMR receipt and its associated reported outcome was examined and data mining based on a Bayesian method of comparison to spontaneous reports for all other vaccines. |
| **Korkmaz, H.A., 2015[**[**19**](#_ENREF_19)**]** | Turkey | 2013 | Unclear | 10 gestational weeks | Active follow-up up to six months of age regarding serology | At 1 months of age positive IgG, at 2 months of age positive IgM, at 6 months of age negative IgM, no virus PCR performed, no further anomalies, but raised liver enzymes, returning to normal at 2 months of age | No |  |

**Appendix table 3. Studies of pregnant women scheduled for induced abortion who agreed to be vaccinated beforehand**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author, year** | **Location, recruitment year(s), publication type** | | **Vaccine**  **R/MR/MMR, rubella strain** | **N(%) susceptible,**  **N(%) immune,**  **N(%) unknown** | **N (% ) vaccinated by timing of vaccination** | **N followed up for (CRS/CRI)**  **By timing of vaccination** | **Type and N outcomes** | **Virological test for vaccine strain done?** | **Comments** |
| **Furukawa, T., 1969 [**[**20**](#_ENREF_20)**]** | | Nagoya, Japan | RA 27/3 (10 women) Cendehill (5 women) | 7 susceptible  8 borderline | All women were vaccinated in 1st trimester | NK | 1 spontaneous abortion, no other adverse effects. Examination of the products of conception for presence of rubella virus and for histologic abnormalities was negative in all cases. The results of all tests, including those of suspensions, of deciduas, chorion, and fetus, were negative. |  | volunteers from an abortion clinic with low or absent HI antibody vaccinated. |
| **Vaheri, A.,**  **1972[**[**21**](#_ENREF_21)**]** | | Finland, 1969, journal article | HPV-77(12) (29 susceptible women),  HPV-77(5) (6 susceptible women) Women scheduled for abortion | 35 women vaccinated | 35 (100%) post conception, 14 weeks maximum gestational age at vaccination | 35 followed up with interview at 6 weeks after vaccination. Serum specimens were obtained from each subject before vaccination, 2-3 weeks later and again 6-9 weeks after vaccination. Throat and nasopharyngeal swabs for virus isolation were collected from 8-36 days after vaccination. | 13/35 virus isolated from throat or nasopharyngeal swab  13/22 virus isolated from cervical swab  5/24 viremia in those who seroconverted  2/15 virus in appendix  6/35 placental tissue virus isolations | Not reported | A single virus isolation was made from fetal tissue. This was obtained from the kidney homogenate of a fetus obtained from a 22-year-old woman vaccinated on the 55th day of gestation who had an induced abortion 24 days later. Virus was recovered in two laboratories and not in the third.’ p.1072  Preliminary findings presented in Vaheri, A. 1969[[22](#_ENREF_22)] |
| **Bernstein, D.I., 1973[**[**23**](#_ENREF_23)**]** | | US | RA27/3 | Several women, all susceptible (no details of numbers given) | ‘Several’ women were vaccinated 6-10 weeks after conception (and 10-14 weeks before scheduled abortions) | Products of conception examined via ‘techniques of tissue culture infection, immunofluorescence and hemagglutination-inhibition’. | No rubella antibody activity or infectious virus was recovered in the fetal or placental tissues. | NA | Immunofluorescence revealed the presence of rubella antigen in one placenta. However, no antigen was found in fetal tissues |
| **Bolognese, R. J.,**  **1973[**[**24**](#_ENREF_24)**]** | | US, 1972-1973, Journal article | Cendehill, women scheduled for abortion were vaccinated | 16 (38.1%) susceptible  24 (57.1%) immune  2 (4.76%) borderline (prevaccination titre 8) | 42 (100%) 1st trimester | 40 women were followed up until the abortion.  2 women gave birth and pregnancy outcome recorded | CRS:0  Immune: 0/2, 2 normal term infants have been delivered to immune mothers  Intrauterine infection:  Susceptible: 3/16 (18.75%) ( virus isolated in abortus material) | Yes, by injecting isolated virus and Freedman ‘wild’ strain rubella virus into ear vein of 4 New Zealand white rabbits | When virus isolated in 2 cases was injected into rabbits, titres identical with those of the “wild” strain were recorded. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Vaccine** | **Strain derivation** | **Attenuation** | **Licensure** |
| HPV77, | Army recruits with rubella (1961) | AGMK (77)\*, monkey cell strain |  |
| HPV77.DE5, Merck | As above | AGMK (77); duck embryo (5) | 1969 |
| HPV77DK12, Philips-Roxane | As above | AGMK (77); dog kidney (12) | 1969 |
| Cendehill Smith-Kline | Urine of a case of post natally acquired rubella (1963) | AGMK (3); primary rabbit kidney (51) | 1969 |
| RA27/3, Merck | Kidney of rubella-infected fetus (1964) | Human embryonic kidney(4); WI-38 fibroblast (17-25) | 1979 |

**Appendix table 4 Types of rubella vaccines (supplementary information)**

\*Figures in parentheses indicate number of passages**,**

**Appendix table 5. Risk of bias for cohort studies of rubella vaccinated susceptible pregnant women**

|  |  |  |
| --- | --- | --- |
| **Author** | **Risk of bias due to losses to followup?** | **Risk of reporting bias** |
| ACIP ’71-‘79**[**[**25**](#_ENREF_25)**]** | Moderate | low |
| ACIP ’79-‘88**[**[**26**](#_ENREF_26)**]** | Moderate | low |
| Badilla, X.[[27](#_ENREF_27)] | serious | moderate |
| Da Silva e Sa, G.R.[[28](#_ENREF_28)] | Serious | moderate |
| Emadi, H.[[29](#_ENREF_29)] | moderate | moderate |
| Hamkar, R.[[30](#_ENREF_30)] | Serious | moderate |
| Lina[[2](#_ENREF_2)] | Serious | moderate |
| Pardon, F.[[31](#_ENREF_31)] | moderate | moderate |
| Reyna[[1](#_ENREF_1)] | Moderate | moderate |
| Sato, H. K.[[32](#_ENREF_32)] | moderate | moderate |
| Sheppard, S[[33](#_ENREF_33)]. | moderate | low |
| Castillo-Solorzano, C., 201143 | See individual studies | See individual studies |

**Appendix 2** example of a full search in Medline

Search included: Ovid MEDLINE(R), Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid OLDMEDLINE(R) 1946 to Present

1. Pregnant wom?n.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

2. Maternal.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

3. Mother\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

4. Antenatal.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

5. Wom?n.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

6. Gestation\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

7. Gravid\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

8. Female adolescent\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

9. Prenatal care.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

10. Preconception\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

11. Perinatal.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

12. Maternal health.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

13. Pregnancy.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

14. mother/

15. pregnant woman/

16. exp maternal welfare/

17. exp pregnancy/

18. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17

19. Vaccin\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

20. Immuni\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

21. Inoculat\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

22. Trivalen\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

23. Combin\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

24. Simultan\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

25. Tripl\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

26. Trebl\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

27. exp Vaccines, Attenuated/

28. exp Vaccines, Combined/

29. 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28

30. rubella.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

31. German measles.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

32. MMR\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

33. Triviraten Berna.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

34. Priorix.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

35. Trimovax.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

36. Morupar.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

37. MERUVAX.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

38. exp rubella/

39. 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38

40. 29 and 39

41. 18 and 40

**References**

1 Reyna J, Herbas I, Gomez M, Vidal P, Cruz P, Puente A, Richardson V. Perinatal outcome of inadvertent immunization with the measles-rubella vaccine in pregnant Mexican women during the campaign for the eradication of congenital rubella in 2008. *World Journal of Vaccines* 2011, **1**, 1-4.

2 Lina, M.D. & María Teresa, E. Seguimiento al estado serológico de mujeres embarazadas que recibieron inadvertidamente la vacuna antirrubeólica, Bogotá, Colombia, 2005-2006. *Investig. Andina* 2008, **10**(17), 77-84.

3 Chin, J., Ebbin, A.J., Wilson, M.G. & Lennette, E.H. Avoidance of rubella immunization of women during or shortly before pregnancy. *JAMA* 1971, **215**(4), 632-634.

4 Larson, H.E., Parkman, P.D., Davis, W.J., Hopps, H.E. & Meyer, H.M., Jr. Inadvertent rubella virus vaccination during pregnancy. *New England Journal of Medicine* 1971, **284**(15), 870-873.

5 Mair, H.J. & Buchan, A.R. Rubella vaccination and termination of pregnancy. *British Medical Journal* 1972, **4**(5835), 271-273.

6 Allan, B.C., Hamilton, S.M., Wiemers, M.A., Winsor, H. & Gust, I.D. Pregnancy complicated by accidental rubella vaccination. *Australian & New Zealand Journal of Obstetrics & Gynaecology* 1973, **13**(2), 72-76.

7 Fleet, W.F., Jr., Benz, E.W., Jr., Karzon, D.T., Lefkowitz, L.B. & Herrmann, K.L. Fetal consequences of maternal rubella immunization. *JAMA* 1974, **227**(6), 621-627.

8 Marks, J.S., Serdula, M.K., Halsey, N.A., Gunaratne, M.V., Craven, R.B., Murphy, K.A. *et al.* Saturday night fever: a common-source outbreak of rubella among adults in Hawaii. *American Journal of Epidemiology* 1981, **114**(4), 574-583.

9 Nasiri, R., Yoseffi, J., Khajedaloe, M., Sarafraz Yazdi, M. & Delgoshaei, F. Congenital rubella syndrome after rubella vaccination in 1-4 weeks periconceptional period. *Indian J Pediatr* 2009, **76**(3), 279-282.

10 Ergenoglu, A.M., Yeniel, A.O., Yildirim, N., Kazandi, M., Akercan, F. & Sagol, S. Rubella vaccination during the preconception period or in pregnancy and perinatal and fetal outcomes. *Turkish Journal of Pediatrics* 2012, **54**(3), 230-233.

11 Phillips, C.A., Maeck, J.V., Rogers, W.A. & Savel, H. Intrauterine rubella infection following immunization with rubella vaccine. *JAMA* 1970, **213**(4), 624-625.

12 Ebbin, A.J., Wilson, M.G., Wehrle, P.F., Chin, J., Emmons, R.W. & Lennette, E.H. Rubella vaccination and pregnancy. *Lancet* 1972, **2**(7775), 481-482.

13 Giles, P.F.H., Mackay Scollay, E.M. & Christiansen, K. Rubella antibody titres, rubella vaccination, and the obstetrician. *Australian and New Zealand Journal of Obstetrics and Gynaecology* 1973, **13**(2), 65-71.

14 Colombo, M.L. & Dogliani, P. A case of rubellar embryopathy due to vaccination with unusual features. [Italian] Embriopatia Rubeolica Da Vaccinazione. Un Caso Clinico Con Peculiari Caratteristiche. *Minerva Pediatrica* 1976, **28**(39), 2429-2436.

15 Banatwala, J.E., O'Shea, S., Best, J.M., Nicholls, M.V. & Cooper, K. Transmission of RA27/3 rubella vaccine strain to products of conception. *Lancet* 1981, **1**(8216), 392.

16 Higaki, Y. Inadvertent maternal rubella vaccination in early pregnancy - A case report. *Annales Paediatrici Japonici* 1989, **34**(4), 14-16.

17 Hofmann, J., Kortung, M., Pustowoit, B., Faber, R., Piskazeck, U. & Liebert, U.G. Persistent fetal rubella vaccine virus infection following inadvertent vaccination during early pregnancy. *Journal of Medical Virology* 2000, **61**(1), 155-158.

18 Sukumaran, L., McNeil, M.M., Moro, P.L., Lewis, P.W., Winiecki, S.K. & Shimabukuro, T.T. Adverse Events Following Measles, Mumps, and Rubella Vaccine in Adults Reported to the Vaccine Adverse Event Reporting System (VAERS), 2003-2013. *Clinical Infectious Diseases* 2015, **60**(10), e58-65.

19 Korkmaz, H.A., Arslan, N. & Aydin, A. Presenting with Isolated Hepatitis Caused by Congenital Rubella Infection Due to Maternal Rubella Vaccination. *Journal of Pediatric Infection* 2015, **9**(1), 38-41.

20 Furukawa, T., Miyata, T., Kondo, K., Kuno, K., Isomura, S. & Takekoshi, T. Clinical trials of RA 27-3 (Wistar) rubella vaccine in Japan. *American Journal of Diseases of Children* 1969, **118**(2), 262-263.

21 Vaheri, A. Undesirable properties of rubella vaccines with special reference to their use in women of fertile age. *Scandinavian Journal of Infectious Diseases* 1972, **6**, Suppl 6:24-27.

22 Vaheri, A., Vesikari, T., Oker-Blom, N., Seppala, M., Veronelli, J., Robbins, F.C. *et al.* Transmission of attenuated rubella vaccines to the human fetus. A preliminary report. *American Journal of Diseases of Children* 1969, **118**(2), 243-246.

23 Bernstein, D.I. & Ogra, P.L. FETAL ASPECTS OF RUBELLA IMMUNIZATION IN PREGNANCY. *Abstracts of the Annual Meeting of the American Society for Microbiology* 1973, **73**, 227-227.

24 Bolognese, R.J., Corson, S.L., Fuccillo, D.A., Sever, J.L. & Traub, R. Evaluation of possible transplacental infection with rubella vaccination during pregnancy. *American Journal of Obstetrics & Gynecology* 1973, **117**(7), 939-941.

25 Bart SW, S.H., Preblud SR, Williams NM, Orenstein WA, Bart KJ, Hinman AR, Herrmann KL. & et al. Fetal risk associated with rubella vaccine: an update. *Reviews of Infectious Diseases* 1985, **7**(1), 95-102.

26 Anonymous. Leads from the MMWR. Rubella vaccination during pregnancy--United States, 1971-1988. *JAMA* 1989, **261**(23), 3374-3375, 3383.

27 Badilla, X., Morice, A., Avila-Aguero, M.L., Saenz, E., Cerda, I., Reef, S. *et al.* Fetal risk associated with rubella vaccination during pregnancy. *Pediatric Infectious Disease Journal* 2007, **26**(9), 830-835.

28 da Silva e Sa, G.R., Camacho, L.A., Stavola, M.S., Lemos, X.R., Basilio de Oliveira, C.A. & Siqueira, M.M. Pregnancy outcomes following rubella vaccination: a prospective study in the state of Rio de Janeiro, Brazil, 2001-2002. *Journal of Infectious Diseases* 2011, **204 Suppl 2**, S722-728.

29 Emadi, H., Hajabdolbaghi, M., Rasoolinejad, M., Jafari, S., Khairandish, P., Taheri, L. *et al.* Outcome of pregnancy in pregnant women vaccinated in the mass campaign against measles/rubella in Tehran, Iran. *International Journal of Antimicrobial Agents* 2007, **29**, S288-S289.

30 Hamkar, R., Jalilvand, S., Abdolbaghi, M.H., Esteghamati, A.R., Hagh-Goo, A., Jelyani, K.N. *et al.* Inadvertent rubella vaccination of pregnant women: evaluation of possible transplacental infection with rubella vaccine. *Vaccine* 2006, **24**(17), 3558-3563.

31 Pardon, F., Vilarino, M., Barbero, P., Garcia, G., Outon, E., Gil, C. *et al.* Rubella vaccination of unknowingly pregnant women during 2006 mass campaign in Argentina. *Journal of Infectious Diseases* 2011, **204 Suppl 2**, S745-747.

32 Sato, H.K., Sanajotta, A.T., Moraes, J.C., Andrade, J.Q., Duarte, G., Cervi, M.C. *et al.* Rubella vaccination of unknowingly pregnant women: the Sao Paulo experience, 2001. *Journal of Infectious Diseases* 2011, **204 Suppl 2**, S737-744.

33 Sheppard, S., Smithells, R.W., Dickson, A. & Holzel, H. Rubella vaccination and pregnancy: preliminary report of a national survey. *British Medical Journal Clinical Research Ed.* 1986, **292**(6522), 727.