

LONDON  
SCHOOL of  
HYGIENE  
& TROPICAL  
MEDICINE



LSHTM Research Online

Mcperson, S; (2024) Safety of the Co-Administration of Azithromycin, Albendazole and Ivermectin Versus Standard Treatment Regimens During Mass Drug Administration (MDA) in Ethiopia: A Cluster Randomized Trial. PhD thesis, London School of Hygiene & Tropical Medicine. DOI: <https://doi.org/10.17037/PUBS.04673426>

Downloaded from: <https://researchonline.lshtm.ac.uk/id/eprint/4673426/>

DOI: <https://doi.org/10.17037/PUBS.04673426>

**Usage Guidelines:**

Please refer to usage guidelines at <https://researchonline.lshtm.ac.uk/policies.html> or alternatively contact [researchonline@lshtm.ac.uk](mailto:researchonline@lshtm.ac.uk).

Available under license. To note, 3rd party material is not necessarily covered under this license: <http://creativecommons.org/licenses/by-nc-nd/4.0/>

<https://researchonline.lshtm.ac.uk>

## Appendix 4: AES Surveillance form

3.1. Study ID: |\_\_|\_\_||\_\_||\_\_|\_\_||\_\_||\_\_|\_\_||\_\_|

3.2. Participant Initial \_\_\_\_\_

3.2.1. Dates of first filling-in for surveillance purposes |\_DD\_|\_MM\_|\_YY\_|

3.2.1.1. Which day(s), please underline D1, D2, D3, D4, D5, D6, D7, D8, D9, D10, D11, D12, D13, D14, D15, D16, D17, D18, D19, D20, D21, D22, D23, D25, D26, D27, D28, D29, D20

3.2.2. Place of first filling-in? 1. Survey site 2. Home 3. Other 99. unknown 3.2.3. If other in 4.1.2., specify the place.....

3.2.4. Did you take all the three drugs? 1. Yes 2. No 99. unknown

3.2.5. Did you regurgitate the drugs? 1. Yes 2. No 99. Unknown

3.2.6. When did you take the drugs? |\_DD\_|\_MM\_|\_YY\_|

3.2.7. How did you feel after taking the drugs? 1. Fine (better than before) 2. Same as before 3. Bad 98. Do not know

3.2.7.1. If the respondent says **fine (better than before) for 4.1.8**, review questions under 2.1 “**For complaints or events prior to the treatment” to describe their evolution**. Use the coding; 0 = **None**: the complaint has gone, 1=**Improved**: the complaint is significantly less than before the treatment, 2 = **Ongoing**: the complaint is the same as before the treatment, 3 = **Exacerbated**: the complaint increased after the treatment; to grade them as in the list below

**Events existing before the treatment complaints (tick as necessary)**

- |   |                           |
|---|---------------------------|
| 4.1.8.1.6 Deafness  | 4.1.8.1.6 Deafness        |
| 4.1.8.1.7 Jaundice  | 4.1.8.1.7 Jaundice        |
| 4.1.8.1.8 Weakness  | 4.1.8.1.8 Weakness        |
| 4.1.8.1.9 Fatigue   | 4.1.8.1.9 Fatigue         |
| 4.1.8.1.10 Nausea   | 4.1.8.1.10 Nausea         |
| 4.1.8.1.11 Vomiting   | 4.1.8.1.11 Vomiting       |
| 4.1.8.1.12 Diarrhoea  | 4.1.8.1.12 Diarrhoea      |
| 4.1.8.1.13 Abdominal pain                                   | 4.1.8.1.13 Abdominal pain |
| 4.1.8.1.5 Tiredness   | <b>Grade</b>              |
| 4.1.8.1.14 Flatulence/dyspepsia                             |                           |
| 4.1.8.1.15 Constipation                                     |                           |
| 4.1.8.1.16 Joint/muscular pain                              |                           |
| 4.1.8.1.17 Swelling of (upper/lower) limbs                  |                           |
| 4.1.8.1.18 Swelling of eyelids/abnormal feeling in the eyes |                           |
| 4.1.8.1.19 Rash/plaque                                      |                           |
| 4.1.8.1.20 Scrotal reaction                                 |                           |

- 4.1.8.1.21 Skin nodules
- 4.1.8.1.22 Worm expulsion
- 4.1.8.1.23 Haematuria
- 4.1.8.1.24 Lymphoedema
- 4.1.8.1.25 Elephantiasis
- 4.1.8.1.26 Hydrocele
- 4.1.8.1.27 Palpitation/tachycardia
- 4.1.8.1.28 Orthostatic hypotension
- 4.1.8.1.29 Others

4.1.8.1.30 **If other specify**.....  
 .....  
 .....

3.2.7.2. Did the respondent experience complaints after taking the 3 drugs? 1. Yes 2. No 99. unknown

3.2.7.3. If yes, which one(s)? (See questions under 4.1.8.1).....  
 .....  
 .....

**3.2.7.4.** How would you qualify your main complaint (see questions under 4.1.8.2), after taking the 3 drugs **1 = Improved 2 = Ongoing 3 = Exacerbated 4= Resolved**

3.2.7.5. If the respondent says **Bad (worsened than before treatment) for 4.1.8,** review questions under 2.1 **“For complaints or events to prior to the treatment” to describe their evolution.** Use the coding; 0 = **did not feel sick,** 1=**mild,** 2 = **Moderate,** 3 = **Major/severe;** to grade them as in the list below

3.2.7.6.

**Adverse event due to worsened existing symptoms before treatment**

**Symptoms/signs when did the side effects appeared Evaluation Code**

**D1 D2 D3 D4 D5 D8 D2 D8**

- 4.1.8.5.1 Fever
- 4.1.8.5.2 Itching/ground itch
- 4.1.8.5.3 Headaches
- 4.1.8.5.4 Dizziness
- 4.1.8.5.5 Tiredness
- 4.1.8.5.6 Deafness
- 4.1.8.5.7 Jaundice
- 4.1.8.5.8 Weakness

- 4.1.8.5.9 Fatigue
- 4.1.8.5.10 Nausea
- 4.1.8.5.11 Vomiting
- 4.1.8.5.12 Diarrhoea
- 4.1.8.5.13 Abdominal pain
- 4.1.8.5.14 Flatulence/dyspepsia
- 4.1.8.2.15 Constipation
- 4.1.8.5.16 Joint/muscular pain
- 4.1.8.5.17 Swelling of (upper/lower) limbs
- 4.1.8.5.18 Swelling of eyelids/abnormal feeling in the eyes
- 4.1.8.5.19 Rash/plaque
- 4.1.8.5.20 Scrotal reaction
- 4.1.8.5.21 Skin nodules
- 4.1.8.5.22 Worm expulsion
- 4.1.8.5.23 Haematuria
- 4.1.8.5.24 Lymphoedema
- 4.1.8.5.25 Elephantiasis
- 4.1.8.5.26 Hydrocele
- 4.1.8.5.27 Palpitation/tachycardia
- 4.1.8.5.28 Orthostatic hypotension
- 4.1.8.5.29 Others
- 4.1.8.5.30 If other specify.....

**NB: FOR REPORTED SEVERE SIDE EFFECT, COMPLETE THE QUESTIONS UNDER 4.3**

**3.3. Adverse events after taking the three drugs be captured in the questions that follows:** defined as;  
**1 = mild:** easily tolerated, does not interfere with daily activity, **2 = moderate :** uncomfortable enough to interfere with daily activity, **3 = severe :** precludes daily activity,**Symptoms/signs**

- 4..2.1 Fever
- 4.2.2 Itching/ground itch 4.2.3 Headaches
- 4.2.4 Dizziness
- 4.2.5 Tiredness
- 4.2.6 Deafness
- 4.2.7 Jaundice
- 4.2.8 Weakness
- 4.2.9 Fatigue

- 4.2.10 Nausea
- 4.2.11 Vomiting
- 4.2.12 Diarrhoea
- 4.2.13 Abdominal pain
- 4.2.14 Flatulence/dyspepsia 4.2.15 Constipation
- 4.2.16 Joint/muscular pain
- 4.2.17 Swelling of (upper/lower) limbs

**Adverse Events after taking the three drugs**

**When did the side effects appear**

**Evaluation**

**D1 D2 D3 D4 D5 D8 D2 D8 D9 D10 D11 D12 D13 D14 D15 D30**

4.2.18 Swelling of eyelids/abnormal feeling in the eyes

4.2.19 Rash/plaque

4.2.20 Scrotal reaction

4.2.21 Skin nodules

4.2.22 Worm expulsion

4.2.23 Haematuria

4.2.24 Lymphoedema

4.2.25 Elephantiasis

4.2.26 Hydrocele

4.2.27 Palpitation/tachycardia

4.2.28 Orthostatic hypotension

4.2.29 Others

4.2.30 **If other specify**.....

.....

**NB: FOR REPORTED SEVERE SIDE EFFECT, COMPLETE THE QUESTIONS UNDER 4.3**