

TTO (5% v/w) gel Tungiasis Trial – CRF

Subject Study ID-no: \_\_\_\_\_



## Case Report Form (CRF)

**Treatment of tungiasis using a 5% v/w tea tree oil (TTO) gel: A randomised, controlled, proof-of-principle trial**

**Subject Study ID:**

Investigator signature\_\_\_\_\_

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## A. Recruitment Form

Please complete this form for every child who is identified as a potential participant in the TTO (5% v/w) gel tungiasis Trial

Investigator: \_\_\_\_\_

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ [dd/mm/yyyy]

School: \_\_\_\_\_

Question	Response (tick one)
1. Has the child been identified as having active embedded jiggers? - If No, excuse participant - If Yes, proceed	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Is the child aged between 6 and 15 years? - If No, excuse participant - If Yes, proceed	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Explain the study protocol to the caregiver (and the child if appropriate) with the aid of the Participant Information Sheet. - Once done, tick 'Done' and proceed	<input type="checkbox"/> Done
4. Is the caregiver able and willing to provide written informed consent for the child to take part in the study? - If No, record reason (if given) and excuse participant _____ - If Yes, proceed	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Is the caregiver able and willing to be contacted by telephone (voice call and SMS) after the initial assessment?	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. Is the child willing to participate in the study? - If No, excuse participant - If Yes, ask child to fill in Written Assent if aged ≥12 years, then proceed	<input type="checkbox"/> Yes <input type="checkbox"/> No
7. Ensure that the child's caregiver has signed informed consent for the child to participate in the study - If 'Done', proceed to Eligibility Assessment Form - If consent was not given, provide reason below (if given) and excuse participant _____	<input type="checkbox"/> Done <input type="checkbox"/> Consent not given

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## B. Eligibility Assessment Form

Please complete this form for every participant who is recruited to the TTO (5% v/w) gel tungiasis trial. This form is used to assess whether the participant meets the criteria to be eligible for enrolment into the study.

Investigator: \_\_\_\_\_ Date assessed: \_\_\_\_/\_\_\_\_/\_\_\_\_ [dd/mm/yyyy]

School: \_\_\_\_\_

### Study Eligibility Criteria

#### Inclusion criteria

Please tick 'Yes' or 'No' for each item.

Both 2 items must be marked 'Yes' for the child to be eligible for enrolment.

Inclusion criteria	Yes	No
1. Is the child aged from 6–15 years with at least 1 viable (stage II and Stage III) lesion according to the Fortaleza classification on the child's feet? <i>Perform clinical examination of the lesions and confirm their viability based on the four viability signs using the handheld digital microscope. Refer to Figure 1 and Figure 2 on page 10 and 11 of Case Report Form.</i>	<input type="checkbox"/>	<input type="checkbox"/>
2. Is the caregiver able and willing to provide written informed consent for the child to take part in the study?	<input type="checkbox"/>	<input type="checkbox"/>

#### Exclusion Criteria

Please tick 'Yes' or 'No' for each item.

All items must be marked 'No' for the child to be eligible for enrolment

Exclusion criteria	Yes	No
1. Are there any cluster lesions (more than 3 lesions together) and manipulated lesions?	<input type="checkbox"/>	<input type="checkbox"/>
2. Are there any complicated lesions (severe) requiring antibiotic treatment?	<input type="checkbox"/>	<input type="checkbox"/>
3. Do the caregivers intend to change their place of residence during the study period?	<input type="checkbox"/>	<input type="checkbox"/>
4. Has the child used <u>any medication</u> (systemic or topical drugs medication) in the past week? This could include antibiotics, prescription or non-prescription medications, creams, ointments, medicated wash products, etc.  If Yes, please tick all that apply and provide name of medication (if known). <input type="checkbox"/> Oral medication (specify) _____ <input type="checkbox"/> Cream/ointment (specify) _____ <input type="checkbox"/> Anti-itch preparation, e.g. steroid (specify) _____ <input type="checkbox"/> other (specify) _____	<input type="checkbox"/>	<input type="checkbox"/>
5. Does the child have a known history of allergy to any of the study medications listed below?  If Yes, please tick all that apply. <input type="checkbox"/> Potassium permanganate <input type="checkbox"/> Tea tree oil or other essential oils	<input type="checkbox"/>	<input type="checkbox"/>

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**Eligibility outcome**

The child is eligible for enrolment into the TTO (5% v/w) gel Tungiasis Trial only if they meet all of the inclusion criteria and do not meet any of the exclusion criteria.

For an eligible child, the answer must be 'Yes' to question 1 and 'No' to question 2 below.

	Yes	No
1. Does the child <u>meet all the Inclusion Criteria</u> (answered 'Yes' to both 2 questions on page 1)?	<input type="checkbox"/>	<input type="checkbox"/>
2. Does the child <u>meet any of the Exclusion criteria</u> (answered 'Yes' to any of the 5 questions on pages 2)?	<input type="checkbox"/>	<input type="checkbox"/>

- The participant is ☐ **Not eligible** for the trial
- Please excuse child and caregiver
- ☐ Eligible for the trial but will not be randomized due to other reasons
- Please specify reason: \_\_\_\_\_
  - \_\_\_\_\_
- ☐ **Eligible** for the trial and will be randomized
- Proceed to Baseline Assessment form

Form completed by: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ [dd/mm/yyyy]

Signature: \_\_\_\_\_

Investigator signature \_\_\_\_\_

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## C. Baseline Assessment

Please complete this assessment form at the participant's first visit (Day 0, Week 0).

Investigator: \_\_\_\_\_ Date assessed: \_\_\_\_/\_\_\_\_/\_\_\_\_ [dd/mm/yyyy]

School: \_\_\_\_\_

### Participant details

#### Demographics

Clinical Assessment 1 - Demographics	Response
Age	
Sex	<input type="checkbox"/> Male <input type="checkbox"/> Female
Date of Informed Consent from legal caregiver (dd/mm/yyyy)	____/____/____
School	
Usual place(s) of residence	<input type="checkbox"/> Rural <input type="checkbox"/> Remote
Usual place(s) of residence (name of suburb, town or community)	_____ _____

#### Physical Examination

Please record any existing medical conditions (e.g. diabetes), allergies, illnesses (e.g. gastroenteritis). Provide further detail in 'comments' below if necessary.

Clinical Assessment 2 – Physical examination					Response
Height (cm)					_____ . ____ cm
Weight (kg)					_____ . ____ kg
Date assessed	Study day	BP	Pulse	Temp.	Comment
____/____/____	Day 1				
____/____/____	Day 4				
____/____/____	Day 5				
____/____/____	Day 7				
____/____/____	Day 10				

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**Medical history**

Medical condition/illness/allergy	Start date (dd/mm/yyyy)	End date (dd/mm/yyyy)	Condition ongoing (Y/N)
	___/___/___	___/___/___	
	___/___/___	___/___/___	
	___/___/___	___/___/___	
	___/___/___	___/___/___	
	___/___/___	___/___/___	

Please record any medications taken by the child in the last 1 week.

Medication name	Indication	Dose	Start date (dd/mm/yyyy)	End date (dd/mm/yyyy)	Ongoing (Y/N)
			___/___/___	___/___/___	
			___/___/___	___/___/___	
			___/___/___	___/___/___	
			___/___/___	___/___/___	

Comments:

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**History of Jiggers**

Please record answers to these questions about jiggers in the child and their community.

Clinical Assessment 1 - History of jiggers	Response
1. How long ago did the child's jiggers start? (tick one)	<input type="checkbox"/> < 1 week <input type="checkbox"/> 1-3 weeks <input type="checkbox"/> 3-6 weeks <input type="checkbox"/> > 6 weeks
2. Has the child previously been diagnosed with jiggers by a health worker or doctor?	<input type="checkbox"/> Yes <input type="checkbox"/> No

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Clinical Assessment 1 - History of jiggers	Response
3. How many times in the past has the child had jiggers? (tick one)	<input type="checkbox"/> 0 <input type="checkbox"/> 1-2 times <input type="checkbox"/> 3-5 times <input type="checkbox"/> >5 times <input type="checkbox"/> unknown
4. Has the child been treated with any jigger's medication <u>at any time in the past?</u>  If Yes, please tick all that apply <input type="checkbox"/> Potassium permanganate (KMnO <sub>4</sub> ) and Vaseline <input type="checkbox"/> Vaseline <input type="checkbox"/> Neem extracts <input type="checkbox"/> Coconut oil <input type="checkbox"/> Other (specify) _____ <input type="checkbox"/> Skin cream/ointment, name unknown <input type="checkbox"/> Oral medication, name unknown If Yes, how long ago did the most recent treatment end? <input type="checkbox"/> < 1 week <input type="checkbox"/> 1-2 weeks <input type="checkbox"/> > 2 weeks	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Has the child been treated with any antibiotics in the last 1 week?  If Yes, what is the name and indication of the antibiotic?  Name: _____ <input type="checkbox"/> Unknown Indication: _____ <input type="checkbox"/> Unknown	<input type="checkbox"/> Yes <input type="checkbox"/> No

## D. Study drug administration

Please record the type of intervention and time of application in this form.

Treatment applied	Amount applied (g)	Date of application dd/mm/yyyy	Time of application 24-hr time
<input type="checkbox"/> Yes <input type="checkbox"/> No		___/___/___	___:___
<input type="checkbox"/> Yes <input type="checkbox"/> No		___/___/___	___:___
<input type="checkbox"/> Yes <input type="checkbox"/> No		___/___/___	___:___
<input type="checkbox"/> Yes <input type="checkbox"/> No		___/___/___	___:___
<input type="checkbox"/> Yes <input type="checkbox"/> No		___/___/___	___:___
<input type="checkbox"/> Yes <input type="checkbox"/> No		___/___/___	___:___

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**E. Clinical and symptomatic assessment -1**

1. Please assess each of the following foot parts for typical jigger lesions (tick if present).

☐ Toe 1- **A**

☐ Toe 2- **B**

☐ Toe 3- **C**

☐ Toe 4- **D**

☐ Toe 5- **E**

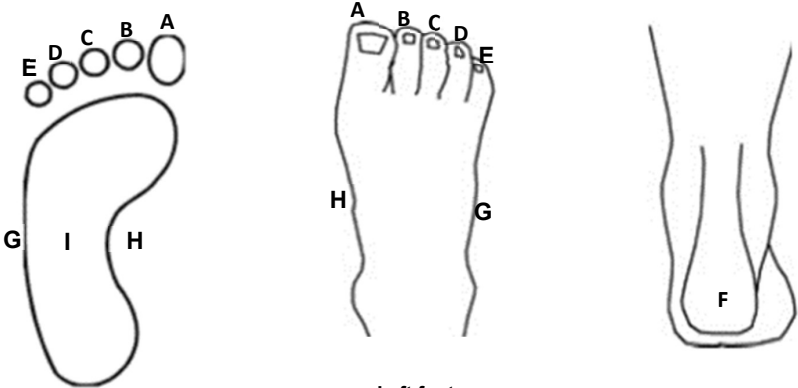
☐ Heel- **F**

☐ Lateral side- **G**

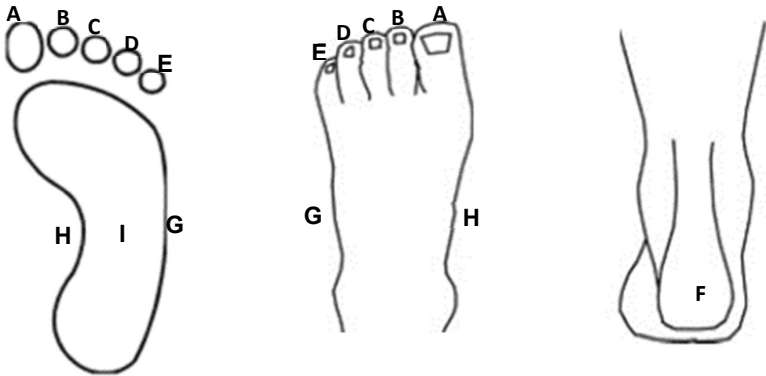
☐ Medial side- **H**

☐ Sole- **I**

Right foot



Left foot



2. Are any viable lesions present on the child's feet?

☐ Yes    ☐ No

3. Mark all sites of viable lesions on the feet diagrams on pages 9 and 10.

☐ Done

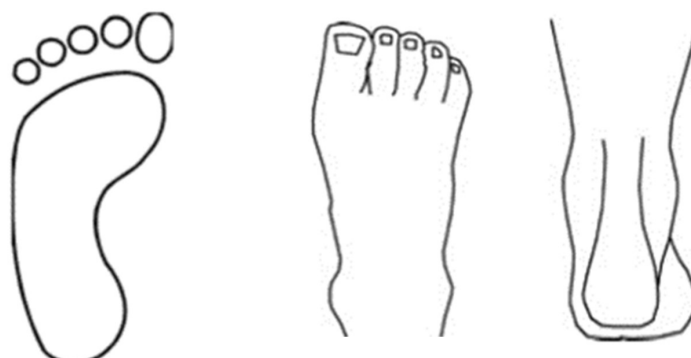


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**E. Clinical and symptomatic assessment -1****Feet diagram – Full**

Mark all sites of active jigger lesions with an X. Clearly label the 2 target sites (see question 4) on the diagrams (e.g. "Target Site 1").

**Right foot****Left foot**

Additional comments:

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**E. Clinical and symptomatic assessment -1**

4. Select and record 2 target lesion in 2 target sites. <i>These should be indicated in the sites that are easily accessible for taking photograph and viability assessment using handheld video microscope. Use a descriptive name like "Toe 1" or "heels" as per question number 1. Mark the location of these sites on the feet diagrams on pages 2.</i>  <b>Target site 1:</b> _____  <b>Target site 2:</b> _____	<input type="checkbox"/> Done
5. Record the names of the target sites on the last page of each of the <i>Clinical Assessment Forms 1, 2 &amp; 3</i> for future reference.	<input type="checkbox"/> Done
6. Photograph each of the 2 viable lesions together with their target sites	<input type="checkbox"/> Done
7. Record the photograph number using stickers on the last page of each of the Clinical Assessment Forms 1, 2 & 3 for future reference.	<input type="checkbox"/> Done
8. Assess the viability of 2 target lesions. Tick all that apply for each site.	
<b>Lesion characteristics</b>	<b>Lesion 1</b>
Localization	
Excretion of faeces (threads)	
Excretion of faeces (liquid)	
Expulsion of eggs	
Pulsation of the flea	
Stage of the lesion	
9. How many <b>Stage II</b> jigger lesions are there on the child's feet (both right (R) and left (L) foot)?	R <input type="text"/> L <input type="text"/>
10. How many <b>Stage III</b> jigger lesions are there on the child's feet (both right (R) and left (L) foot)?	R <input type="text"/> L <input type="text"/>
11. How many <b>numbers of viable lesions</b> (Stages II & III, total) are there on the child's feet?	
12. How many <b>numbers of manipulated lesions (total)</b> are there on the child's feet?	
13. How many <b>numbers of cluster lesions (total)</b> are there on the child's feet?	

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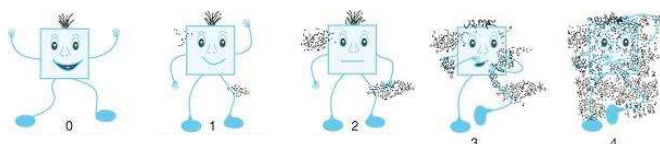
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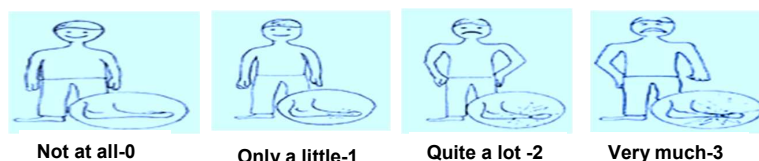
**E. Clinical and symptomatic assessment -1**

14. Ask the child to rate their itching over the last day (24 hours) based on the 'itch man' picture scale (tick one).



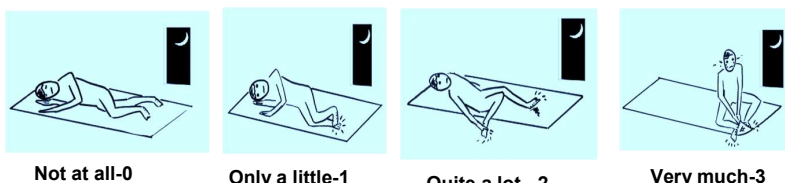
- ☐ 0  
☐ 1  
☐ 2  
☐ 3  
☐ 4

15. Ask the child to rate their pain over the last day (24 hours) based on the 'itch man' picture scale (tick one).



- ☐ 0  
☐ 1  
☐ 2  
☐ 3  
☐ 4

16. Ask the child to rate their sleep disturbance over the last day (24 hours) based on the the following picture scale (tick one).



- ☐ 0  
☐ 1  
☐ 2  
☐ 3  
☐ 4

**Acute pathology examination and scoring**

		Sites on the right foot								
		Toe 1	Toe 2	Toe 3	Toe 4	Toe 5	Heel	Lateral side	Medial side	Sole
Acute pathology	Erythema									
	Warmness									
	Edema									
	Desquamation									
	Fissure									
	Suppuration									
	Ulcer									
	Abscess									
		Sites on the left foot								
		Toe 1	Toe 2	Toe 3	Toe 4	Toe 5	Heel	Lateral side	Medial side	Sole
Acute pathology	Erythema									
	Warmness									
	Edema									
	Desquamation									
	Fissure									
	Suppuration									
	Ulcer									
	Abscess									

Investigator signature \_\_\_\_\_

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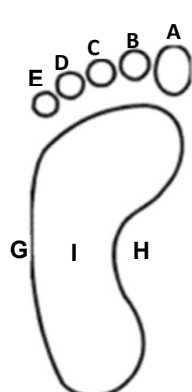


## F. Clinical and symptomatic assessment- 2

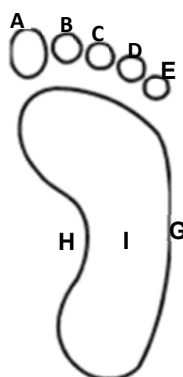
1. Please assess each of the following foot parts for new and existing jigger lesions (tick if present).

☐ Toe 1- **A**
☐ Toe 4- **D**
☐ Lateral side- **G**
☐ Toe 2- **B**
☐ Toe 5- **E**
☐ Medial side- **H**
☐ Toe 3- **C**
☐ Heel- **F**
☐ Sole- **I**

Right foot



Left foot



2. Are any new embedded jiggers present on the child's feet?

☐ Yes

☐ No

3. How many numbers of **newly embedded sand fleas** since the last examination?

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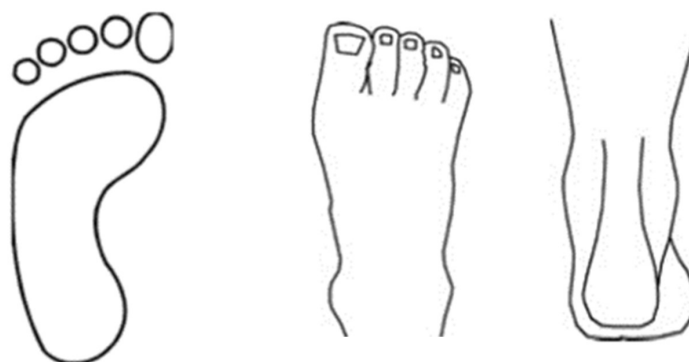
Subject Study ID-no: \_\_\_\_\_

**F. Clinical and symptomatic assessment- 2**

4. Mark all sites of new embedded jiggers and existing viable lesions on the feet diagrams on pages 13 and 14.

☐ Done**Feet diagram – Full**

Mark all sites of active jigger lesions with X and newly embedded jiggers with Y. Clearly label the 2 target sites (see question 4) on the diagrams (e.g. “Target Site 1”).

**Right foot****Left foot**

Additional comments:

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**F. Clinical and symptomatic assessment- 2**

5. Follow the selected viable lesions together with their target sites. <i>These should be indicated in the sites that are easily accessible for taking photograph and viability assessment using handheld video microscope. Use a descriptive name like "Toe 1" or "heels" as per question number 1. Mark the location of these sites on the feet diagrams on pages 2.</i>  <b>Target site 1:</b> _____  <b>Target site 2:</b> _____	<input type="checkbox"/> Done
6. Record the names of the target sites on the last page of each of the <i>Clinical Assessment Forms 1, 2 &amp; 3</i> for future reference.	<input type="checkbox"/> Done
7. Photograph the 2 target lesions together with their target sites	<input type="checkbox"/> Done
8. Record the photograph number using stickers on the last page of each of the Clinical Assessment Forms 1, 2 & 3 for future reference.	<input type="checkbox"/> Done
9. Assess the viability of 2 target lesions. Tick all that apply for each site.	
<b>Lesion characteristics</b>	<b>Lesion 1</b>
Localization	
Excretion of faeces (threads)	
Excretion of faeces (liquid)	
Expulsion of eggs	
Pulsation of the flea	
Stage of the lesion	
10. How many <b>Stage II</b> jigger lesions are there on the child's feet (both right (R) and left (L) foot)?	R <input type="text"/> L <input type="text"/>
11. How many <b>Stage III</b> jigger lesions are there on the child's feet (both right (R) and left (L) foot)?	R <input type="text"/> L <input type="text"/>
12. How many <b>total numbers of viable lesions</b> (stage II & III) are there on the child's feet	

Investigator signature \_\_\_\_\_

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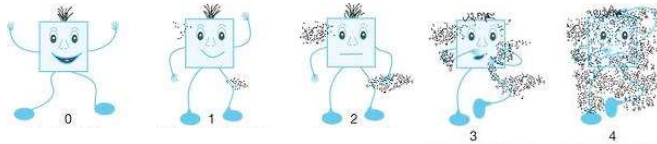
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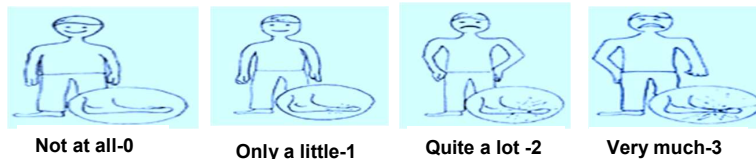
**F. Clinical and symptomatic assessment- 2**

13. Ask the child to rate their itching over the last day (24 hours) based on the 'itch man' picture scale (tick one).



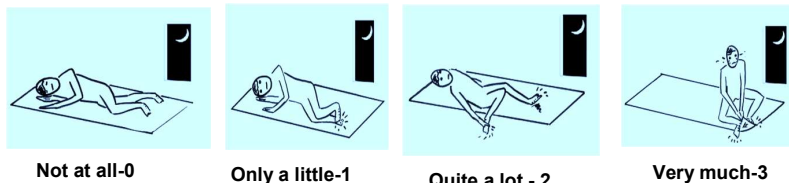
- ☐ 0  
☐ 1  
☐ 2  
☐ 3  
☐ 4

14. Ask the child to rate their pain over the last day (24 hours) based on the 'itch man' picture scale (tick one).



- ☐ 0  
☐ 1  
☐ 2  
☐ 3  
☐ 4

15. Ask the child to rate their sleep disturbance over the last day (24 hours) based on the following picture scale (tick one).



- ☐ 0  
☐ 1  
☐ 2  
☐ 3  
☐ 4

**Acute pathology examination and scoring**

		Sites on the right foot								
		Toe 1	Toe 2	Toe 3	Toe 4	Toe 5	Heel	Lateral side	Medial side	Sole
Acute pathology	Erythema									
	Warmness									
	Edema									
	Desquamation									
	Fissure									
	Suppuration									
	Ulcer									
	Abscess									
		Sites on the left foot								
		Toe 1	Toe 2	Toe 3	Toe 4	Toe 5	Heel	Lateral side	Medial side	Sole
Acute pathology	Erythema									
	Warmness									
	Edema									
	Desquamation									
	Fissure									
	Suppuration									
	Ulcer									
	Abscess									

Investigator signature \_\_\_\_\_

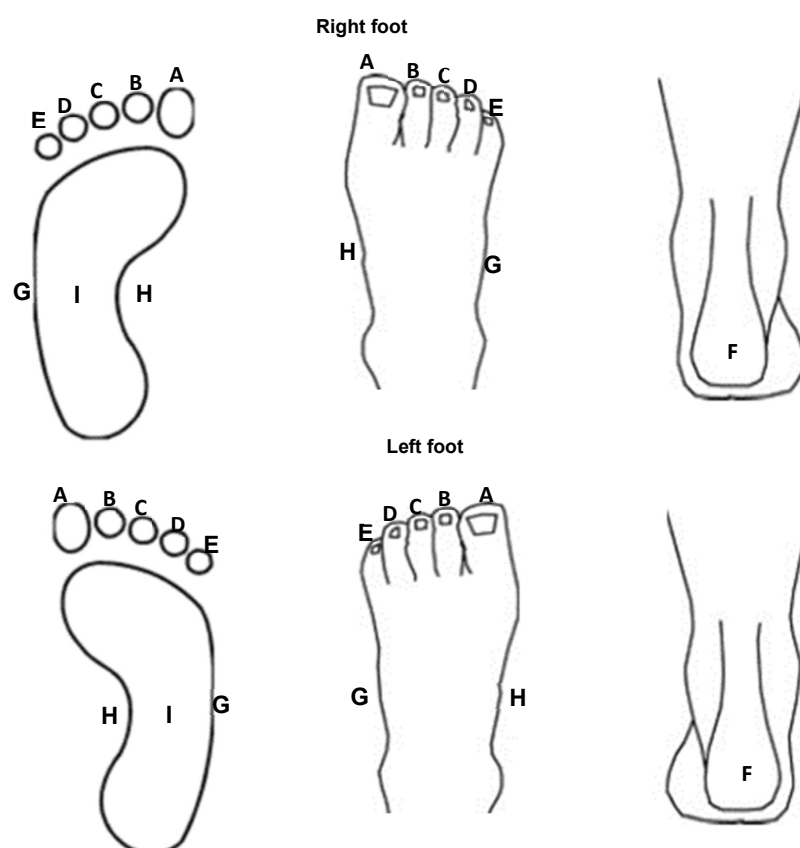
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### G. Clinical and symptomatic assessment - 3

1. Please assess each of the following foot parts for new and existing jigger lesions (tick if present).

☐ Toe 1- **A**
☐ Toe 4- **D**
☐ Lateral side - **G**
☐ Toe 2- **B**
☐ Toe 5- **E**
☐ Medial side - **H**
☐ Toe 3- **C**
☐ Heel- **F**
☐ Sole - **I**


2. Are any new embedded jiggers present on the child's feet?

☐ Yes

☐ No

3. How many numbers of **newly embedded sand fleas** since the last examination?

Investigator signature \_\_\_\_\_

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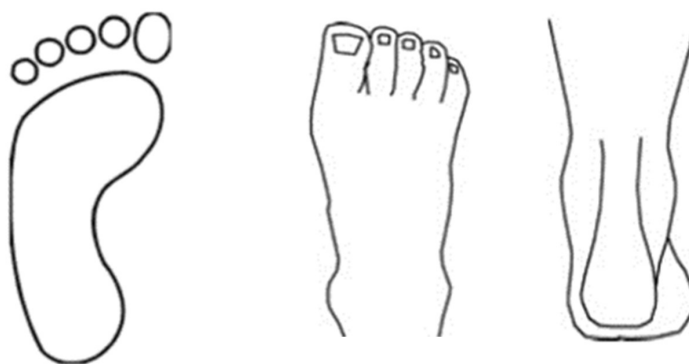
Subject Study ID-no: \_\_\_\_\_

**G. Clinical and symptomatic assessment - 3**

4. Mark all sites of new embedded jiggers and existing viable lesions on the feet diagrams on pages 13 and 14.

☐ Done**Feet diagram – Full**

Mark all sites of active jigger lesions with X and newly embedded jiggers with Y. Clearly label the 2 target sites (see question 4) on the diagrams (e.g. “Target Site 1”).

**Right foot****Left foot**

Additional comments:

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Investigator signature \_\_\_\_\_

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**G. Clinical and symptomatic assessment - 3**

5. Follow the selected viable lesions together with their target sites. <i>These should be indicated in the sites that are easily accessible for taking photograph and viability assessment using handheld video microscope. Use a descriptive name like "Toe 1" or "heels" as per question number 1. Mark the location of these sites on the feet diagrams on pages 2.</i>  <b>Target site 1:</b> _____  <b>Target site 2:</b> _____	<input type="checkbox"/> Done
6. Record the names of the target sites on the last page of each of the <i>Clinical Assessment Forms 1, 2 &amp; 3</i> for future reference.	<input type="checkbox"/> Done
7. Photograph the 2 target lesions together with their target sites	<input type="checkbox"/> Done
8. Record the photograph number using stickers on the last page of each of the Clinical Assessment Forms 1, 2 & 3 for future reference.	<input type="checkbox"/> Done
9. Assess the viability of 2 target lesions. Tick all that apply for each site.	
<b>Lesion characteristics</b>	<b>Lesion 1</b>
Localization	
Excretion of faeces (threads)	
Excretion of faeces (liquid)	
Expulsion of eggs	
Pulsation of the flea	
Stage of the lesion	
10. How many <b>Stage II</b> jigger lesions are there on the child's feet (both right (R) and left (L) foot)?	R <input type="text"/> L <input type="text"/>
11. How many <b>Stage III</b> jigger lesions are there on the child's feet (both right (R) and left (L) foot)?	R <input type="text"/> L <input type="text"/>
12. How many <b>total numbers of viable lesions</b> (stage II & III) are there on the child's feet	

Investigator signature \_\_\_\_\_

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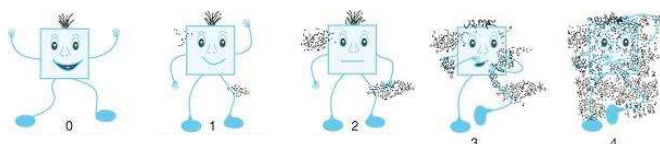
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TTO (5% v/w) gel Tungiasis Trial – CRF

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**G. Clinical and symptomatic assessment - 3**

13. Ask the child to rate their itching over the last day (24 hours) based on the 'itch man' picture scale (tick one).



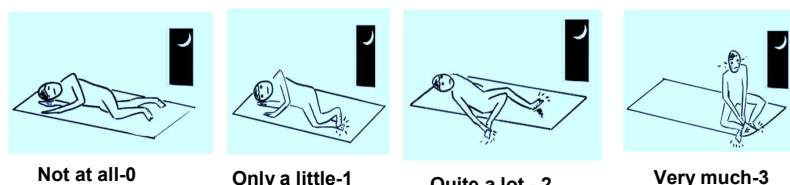
- ☐ 0  
☐ 1  
☐ 2  
☐ 3  
☐ 4

14. Ask the child to rate their pain over the last day (24 hours) based on the 'itch man' picture scale (tick one).



- ☐ 0  
☐ 1  
☐ 2  
☐ 3  
☐ 4

15. Ask the child to rate their sleep disturbance over the last day (24 hours) based on the following picture scale (tick one).



- ☐ 0  
☐ 1  
☐ 2  
☐ 3  
☐ 4


**Acute pathology examination and scoring**

		Sites on the right foot								
		Toe 1	Toe 2	Toe 3	Toe 4	Toe 5	Heel	Lateral side	Medial side	Sole
Acute pathology	Erythema									
	Warmness									
	Edema									
	Desquamation									
	Fissure									
	Suppuration									
	Ulcer									
	Abscess									
		Sites on the left foot								
		Toe 1	Toe 2	Toe 3	Toe 4	Toe 5	Heel	Lateral side	Medial side	Sole
Acute pathology	Erythema									
	Warmness									
	Edema									
	Desquamation									
	Fissure									
	Suppuration									
	Ulcer									
	Abscess									

Investigator signature \_\_\_\_\_

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H. Adverse Event Log

Date of entry	Adverse Event	Grade/Severity	Serious	Date/time of Onset	Date/time of Resolution	Relation to study drugs	Action taken	Treatment given	Outcome
dd/mm/yyyy	Diagnosis (if known) or Signs/symptoms (list one per line)	1=mild 2=moderate 3=severe	(Y/N) *	dd/mm/yyyy 24-hr time	dd/mm/yyyy 24-hr time	1=related 2=not related 3=other Specify	1=none 2=interrupted 3=patient withdrawn 4=medication discontinued 5=other???	(Y/N)	1=resolved 2=resolved w sequelae 3=ongoing 4=death 5=unknown
__/__/__				__/__/__ __:__	__/__/__ __:__				
__/__/__				__/__/__ __:__	__/__/__ __:__				
__/__/__				__/__/__ __:__	__/__/__ __:__				
__/__/__				__/__/__ __:__	__/__/__ __:__				
__/__/__				__/__/__ __:__	__/__/__ __:__				
__/__/__				__/__/__ __:__	__/__/__ __:__				

\*For any Serious Adverse Events, participant must be immediately referred to nearby healthcare facility for medic

Investigator signature\_\_\_\_\_

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## I. Final Study Outcome

Question	Response (tick one)
Has the subject completed the study?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, indicate the completion date dd/mm/yyyy	___/___/___
If NO, specify last follow up date dd/mm/yyyy	___/___/___
What are the reasons for not completing the study?	<input type="checkbox"/> Significant non-compliance
	<input type="checkbox"/> Drug-related AE
	<input type="checkbox"/> Treatment failure
	<input type="checkbox"/> Consent withdrawn
	<input type="checkbox"/> Lost to follow-up
	<input type="checkbox"/> Other (specify)
Remarks	
<b>Investigator's Statement</b>	
<i>I have reviewed the data recorded in this CRF and confirm that the data are complete and accurate</i>	
Investigator (Full name)	
Investigator signature	
Signature Date /dd/mm/yyyy/:	___/___/___

Investigator signature \_\_\_\_\_