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To determine the safety, tolerability and systemic absorption of Diethylcarbamazine (DEC) from a "patch" applied locally to the skin for the diagnosis of Onchocerca volvulus infection (Clinical trials of drugs for onchocerciasis) (Ghana)

Submission date	Recruitment status	[_] Prospectively registered
05/04/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/06/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/04/2016	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
980819

Study information

Scientific Title
To determine the safety, tolerability and systemic absorption of Diethylcarbamazine (DEC) from a "patch" applied locally to the skin for the diagnosis of Onchocerca volvulus infection (Clinical trials of drugs for onchocerciasis) (Ghana)

Study objectives
The patch based on transdermal drug delivery technology is safe and well tolerated in subjects infected with Onchocerca volvulus and results in recognizable and specific skin reactions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ghana Health Service Ethical Review Committee (last approval 30/03/2005)
2. World Health Organization (WHO) Ethics Review Committee (last approval date 21/11/2005)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Onchocerciasis

Interventions
Two types of Diethylcarbamazine (DEC) patches (Onchocerciasis Control Programme [OCP] and Lohmann Therapie-System [LTS]) applied to two groups each of 15 subjects. OCP applied on day

one to one iliac crest after overnight fast. After a study and washout period of four days, the LTS patch applied on the other iliac crest and similar blood sampling repeated.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Diethylcarbamazine

Primary outcome measure
To determine the safety, tolerability and potential utility under field conditions for the diagnosis of onchocerciasis of the LTS patch 2 prototype in subjects known to be infected with Onchocerca volvulus. The utility of LTS patch 2 for field use will depend on the ease of preparation, application and readout of the results.

Secondary outcome measures
1. To compare the positive reaction rates of the OCP and LTS patches as determined at 24 and 30 hours after application
2. To determine the underlying pathology of the skin reactions from the histopathology of skin punch biopsies taken from selected subjects

Overall study start date
12/06/2003

Completion date
01/08/2006

Eligibility

Key inclusion criteria
1. Males in good general health, with O. volvulus infection
2. Written, signed and dated informed consent
3. Age 18 to 55 years
4. Weight over 40 kg
5. Healthy as determined by medical history, physical exam, Electrocardiogram (ECG) and clinical lab results
6. Adequate lab functions:
6.1. White Blood Cell count (WBC) more than 3,500 and 12,000 cells/ml
6.2. Haemogloblin (Hb) more than 11.0 g/dl
6.3. Platelets count more than 110,000 mm^3
6.4. Serum creatinine less than 1.25 x Upper Limit of Normal (ULN)
6.5. Total bilirubin less than 1.25 x ULN
6.6. Aspartate Transaminase (AST)/Serum Glutamic Oxaloacetic Transaminase (SGOT) less than 1.25 x ULN
6.7. Alkaline Phosphatase (AP) more than 1.25 x ULN
7. Skin microfilarial (mf) density of 5 to 15 mg as determined at the iliac crests

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
30

Key exclusion criteria
1. Ocular onchocerciasis
2. Hyper-reactive onchodermatitis
3. Skin lesions over iliac crests
4. Coincidental infection with Mansonella streptocera
5. Significant Electrocardiogram (ECG) abnormalities or history of cardiac abnormality
6. History of drug or alcohol abuse
7. Any other condition that the investigator feels would exclude the subject

Date of first enrolment
12/06/2003

Date of final enrolment
01/08/2006

Locations

Countries of recruitment
Ghana

Switzerland

Study participating centre
World Health Organization
Geneva
Switzerland
CH-1211

Sponsor information

Organisation
UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR)

Sponsor details
World Health Organization
20 Avenue Appia
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Sponsor type
Research organisation

Website
http://www.who.int

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
United Nations Children's Fund (UNICEF)/United Nations Development Programme (UNDP)/World Bank/World Health Organization (WHO) - Special Programme for Research and Training in Tropical Diseases (TDR)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	09/10/2015	Yes	No