

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 05/04/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/06/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/04/2016	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Diagnostic

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(s)

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.

Key secondary outcome(s)

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

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. Haemoglobin (Hb) more than 11.0 g/dl
 - 6.3. Platelets count more than 110,000 mm³
 - 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Male

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)

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

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