

Phase I clinical trial to evaluate the safety and immunogenicity of aluminium hydroxide precipitated autoclaved Leishmania major (Alum-ALM) + Bacillus Calmette-Guerin (BCG) combined with sodium stibo-gluconate (SSG) compared with SSG alone in the treatment of post kala azar dermal leishmaniasis (Sudan)

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 26/03/2008	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

A30468

Study information

Scientific Title

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Dermal leishmaniasis

Interventions

Intervention group: Alum-ALM and BCG combined with sodium stibo-gluconate (SSG)

Control group: Sodium stibo-gluconate (SSG)

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

Aluminium hydroxide precipitated autoclaved Leishmania major (Alum-ALM) + Bacillus Calmette-Guerin (BCG) + sodium stibo-gluconate (SSG)

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

07/10/2003

Completion date

01/01/2004

Eligibility**Key inclusion criteria**

1. Males and females 7 - 60 years
2. Skin rash of greater than six months duration following a history of successful treatment for Visceral Leishmaniasis (VL)
3. Absence of other skin conditions
4. Positive Direct Agglutination Rest (DAT) or rk39
5. Willing for hospitalisation at Khartoum for 90 days
6. Informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

30

Key exclusion criteria

1. Pregnant or lactating women
2. Concurrent/chronic illness
3. Known allergy to vaccine components
4. Other allergies requiring steroids and Levamisole
5. Known immunological deficiency-including human immunodeficiency virus (HIV)
6. Concurrent participation in any other drug or vaccine trial
7. Known or planned vaccination within one month prior to study

Date of first enrolment

07/10/2003

Date of final enrolment

01/01/2004

Locations

Countries of recruitment

Sudan

Switzerland

Study participating centre

20, Avenue Appia

Geneva -27

Switzerland

CH 1211

Sponsor information

Organisation

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

Sponsor details

20, Avenue Appia

Geneva -27

Switzerland

CH 1211

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