

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	☐ Prospectively registered
Registration date 07/06/2005	Overall study status Completed	☐ Protocol
Last Edited 26/03/2008	Condition category Infections and Infestations	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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