ISRCTN88133880 https://doi.org/10.1186/ISRCTN88133880

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

Registration date
07/06/2005

Last Edited
26/03/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] 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

Study design
Randomised controlled trial

Primary study design
Interventional

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