ISRCTN88861431 https://doi.org/10.1186/ISRCTN88861431

Study of safety and immunogenicity of Measles vaccine (Rouvax®) administered by transcutaneous route (France)

Submission date	Recruitment status	[_] Prospectively registered
25/11/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/11/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
26/03/2008	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Martin Friede

Contact details
20, Avenue Appia
Geneva-27
Switzerland
CH 1211
+41 (0)22 791 4398
friedem@who.int

Additional identifiers

Protocol serial number
RPC 037

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received on the 23rd March 2004.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Vaccine/immunisation

Interventions
Intervention: 1 dose of Rouvax® vaccine administered to the skin of the shoulder after stripping (abrading) the skin
Control: 1 dose of Rouvax® administered by injection

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Measles vaccine (Rouvax®)

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
23/03/2005

Eligibility

Key inclusion criteria
1. Healthy adults between 18 and 22 years of age of haplotype HLA-A201 who have previously been immunised against measles and for whom the anti-measles antibodies are low
2. Female participants must be under contraception

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Previous infection with measles
2. Contra-indications to the use of Rouvax® vaccine
3. Hypersensitivity to egg proteins
4. Human Immunodeficiency Virus (HIV) seropositive
5. Treatment with corticosteroids or immunosuppressors in 15 days prior to enrolment
6. Exposure of back-skin to sun in 15 days prior to enrolment
7. Dermatological pathology on back
8. Acute and evolutive disease
9. Blood donation in three months prior to enrolment
10. In a period of exclusion following previous clinical trials
11. Having received 3800 or more Euros in preceeding 12 months from participation in clinical trials

Date of first enrolment
23/03/2004

Date of final enrolment
23/03/2005

Locations

Countries of recruitment
France

Switzerland

Study participating centre
20, Avenue Appia
Geneva-27
Switzerland
CH 1211

Sponsor information

Organisation
World Health Organization (WHO)/Department of Immunisation, Vaccines and Biologicals (IVB) (Switzerland)

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
World Health Organization (WHO)/Department of Immunisation, Vaccines and Biologicals (IVB) (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration