ISRCTN34213833 https://doi.org/10.1186/ISRCTN34213833

A study to investigate whether topical tacrolimus can prevent delayed-type hypersensitivity to nickel in patients with known nickel contact allergy

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
03/01/2020

Condition category
Skin and Connective Tissue Diseases

[_] 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
N0241117754

Study information

Scientific Title
The effect of topical tacrolimus on nickel contact dermatitis elicitation reactions

Study objectives
To investigate whether the normal delayed-type contact allergic reaction to a known contact allergen, in this case nickel, can be prevented by pretreating the skin to be tested with topical tacrolimus, as an immunomodulator.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-blinded vehicle-controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Skin and Connective Tissue Diseases: Nickel allergy

Interventions
Patients will pre-treat an area on one upper arm with topical tacrolimus ointment for 1 week and simultaneously they will treat a similar area on the opposite upper arm with vehicle in ointment form. Identical patches of a series of nickel dilutions will be applied to both topically treated areas. These patches will be removed 48 h later and readings of the tested areas will be performed and any positive results graded according to the European Contact Dermatitis Group criteria.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The patch test results will be assessed visually and a record will be made of whether topical tacrolimus has prevented a delayed-type hypersensitivity reaction, when compared to the vehicle treated area tested, and if so at which nickel concentrations.

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

Completion date
01/11/2003

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/2002

Date of final enrolment
01/11/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Dermatology
London
United Kingdom
W2 1NY

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
St Mary's NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration