

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	☐ Prospectively registered
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 03/01/2020	Condition category Skin and Connective Tissue Diseases	☐ 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