

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	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/01/2020	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

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 measure

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.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/11/2002

Completion date

01/11/2003

Eligibility**Key inclusion criteria**

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

10-20 patients.

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**

England

United Kingdom

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

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.doh.gov.uk>

Funder(s)

Funder type
Government

Funder Name
St Mary's NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration
2003 results in: <https://doi.org/10.1046/j.1365-2133.149.s64.9.x> (added 03/01/2020)

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration