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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

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