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A placebo-controlled double blind preliminary trial to study the efficacy and safety of Gelclair in controlling the symptoms of oral lichen planus

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
11/08/2016	Skin and Connective Tissue Diseases	[ ] 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
N0013137372

Study information

Scientific Title
A placebo-controlled double blind preliminary trial to study the efficacy and safety of Gelclair in controlling the symptoms of oral lichen planus

Study objectives
To compare the symptom control offered by Gelclair vs placebo in patients with symptomatic oral lichen planus. Gelclair will be a useful adjunct in the management of pain associated with oral lichen planus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Skin and Connective Tissue Diseases: Oral lichen planus

Interventions
Patients presenting to the department of oral medicine will be assessed for their suitability for inclusion within the trial. They will be invited to take part if they are diagnosed with lichen planus not due to a specific cause and confirmed histologically. They will be paired according to their symptoms at the time of presentation and randomised to either Gelclair or placebo. Normal treatment for lichen planus in the form of topical steroids will be prescribed as normal.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Gelclair

Primary outcome measure
Gelclair is of use in managing the symptoms of pain in oral lichen planus. Primary response criteria: symptom control over an eight-week period, usage of topical corticosteroids (patient-controlled).

Secondary outcome measures
Tolerability and acceptability

Overall study start date
15/01/2004

Completion date
15/06/2005

Eligibility

Key inclusion criteria
30 patients in control (placebo) group, 30 in Gelclair. Matched by symptoms and extent of disease at initial presentation.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
60

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
15/01/2004

Date of final enrolment
15/06/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oral Medicine Department
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Department of Health

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

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Guy's and St Thomas' NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration