

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

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Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/08/2016	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

Protocol serial number

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

Study type(s)

Not Specified

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(s)

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).

Key secondary outcome(s)

Tolerability and acceptability

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Oral Medicine Department

London

United Kingdom

SE1 9RT

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration