

A pilot study to evaluate the use of pregabalin in the management of burning mouth syndrome

Submission date 16/04/2008	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/08/2008	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/04/2012	Condition category Signs and Symptoms	<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
STH 13781

Study information

Scientific Title

Study objectives

An open label study to evaluate the use of pregabalin in managing patients with burning mouth syndrome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North Sheffield Research Ethics Committee. Date of approval: 19/07/2004 (ref: 04/q2308/57)

Study design

Single-arm, open label, pilot study.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Burning mouth syndrome

Interventions

The 12-week intervention is in four stages:

Stage 1: Pregabalin (oral), two weeks at 75 mg twice a day (bd)

Stage 2: Either maintain 75 mg bd or increase to 150 mg bd for a further 2 weeks

Stage 3: Either maintain the previous dose or increase (150 mg/ 300 mg bd) for a further 2 weeks

Stage 4: Maintain the previous dose or consider increase (150 mg/ 300 mg bd) for a further 6 weeks

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Pregabalin

Primary outcome(s)

The following will be assessed pre-visit and at 2, 4, 6, and 12 weeks:

1. Severity of symptoms, assessed by a visual analogue scale (VAS)
2. Global impression of change

Key secondary outcome(s)

Medication side effects, recorded until 12 weeks.

Completion date

31/12/2008

Reason abandoned (if study stopped)

"Participant recruitment issue"

Eligibility

Key inclusion criteria

1. Both males and females
2. Adults (over 16)
3. Diagnosis of burning mouth syndrome

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Reduced renal function
2. Females who are pregnant or breast feeding
3. Patients already taking anti-convulsants or anti-depressants
4. Hereditary problems of galactose intolerance, lapp lactase deficiency and glucose-galactose malabsorption

Date of first enrolment

01/06/2005

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

School of Clinical Dentistry

Sheffield

United Kingdom

S10 2TA

Sponsor information

Organisation

Sheffield Teaching Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/018hjpz25>

Funder(s)**Funder type**

Industry

Funder Name

Educational grant from Pfizer (USA)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes