

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Non randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please contact Mrs J Parkin at j.a.parkin@sheffield.ac.uk for trial details.

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 measure

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

Secondary outcome measures

Medication side effects, recorded until 12 weeks.

Overall study start date

01/06/2005

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

Age group

Adult

Sex

Both

Target number of participants

20

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

England

United Kingdom

Study participating centre

School of Clinical Dentistry

Sheffield

United Kingdom

S10 2TA

Sponsor information

Organisation

Sheffield Teaching Hospitals NHS Foundation Trust (UK)

Sponsor details

Research Department

3rd Floor

Pegasus House

463a Glossop Road

Sheffield

England

United Kingdom

S10 2QD

Sponsor type

Hospital/treatment centre

Website

<http://www.sth.nhs.uk>

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Educational grant from Pfizer (USA)

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