

Assessment of controlled release buccal inserts containing pilocarpine hydrochloride: a multi-centre, double-blind, placebo-controlled, randomised, cross-over study in patients diagnosed with Sjögren's Syndrome

Submission date 23/09/2002	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 23/09/2002	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 24/05/2016	Condition category Musculoskeletal Diseases	☐ 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

Protocol serial number

PILO-BUC-002

Study information

Scientific Title

Assessment of controlled release buccal inserts containing pilocarpine hydrochloride: a multi-centre, double-blind, placebo-controlled, randomised, cross-over study in patients diagnosed with Sjögren's Syndrome

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Multi-centre double-blind placebo-controlled randomised cross-over study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Sjögren's Syndrome

Interventions

This trial is a 'cross-over' study with four treatment cycles. For each treatment cycle, patients will be provided with 12 buccal inserts, containing one of the following: 2.5, 5 or 10 mg pilocarpine or placebo. A treatment cycle is four days long, however, there will be a three day washout period between each new dose. The buccal insert is a hydrogel polymer with pilocarpine dispersed throughout the matrix. Each buccal insert should be inserted high in the upper buccal sulcus between the buccal mucosa and gingivae towards the back of the mouth and remain in situ for at least three hours. One buccal insert should be inserted three times daily in the period between meals.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2002

Eligibility

Key inclusion criteria

Approximately 30 patients with primary or secondary Sjögren's Syndrome, as diagnosed by the modified European Diagnostic Classification, will be enrolled into the study, to accrue 25 evaluable patients

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2002

Date of final enrolment

31/12/2002

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

The University of Birmingham

Birmingham

United Kingdom

B4 6NN

Sponsor information

Organisation

Controlled Therapeutics (Scotland) Ltd

ROR

<https://ror.org/03e9kb581>

Funder(s)**Funder type**

Industry

Funder Name

Controlled Therapeutics (Scotland) Ltd (UK)

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

Not provided at time of registration