

# 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

<b>Submission date</b> 23/09/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 23/09/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 24/05/2016	<b>Condition category</b> Musculoskeletal Diseases	<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

**Contact name**  
Mr John Hamburger

**Contact details**  
The University of Birmingham  
School of Dentistry  
St Chad's Queensway  
Birmingham  
United Kingdom  
B4 6NN  
+44 (0)121 237 2888  
[j.hamburger@bham.ac.uk](mailto:j.hamburger@bham.ac.uk)

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### **Study design**

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

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Treatment

### **Participant information sheet**

### **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 measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/2002

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

30

**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**

England

United Kingdom

**Study participating centre**  
**The University of Birmingham**  
Birmingham  
United Kingdom  
B4 6NN

## Sponsor information

**Organisation**  
Controlled Therapeutics (Scotland) Ltd

**Sponsor details**  
1 Redwood Place  
Peel Park Campus  
East Kilbride  
United Kingdom  
G74 5PB

**Sponsor type**  
Industry

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

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Controlled Therapeutics (Scotland) Ltd (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