

Bell's palsy: Early aciclovir and/or prednisolone in Scotland

Submission date 10/08/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 16/08/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/10/2009	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.dundee.ac.uk/bells/>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 02/09/04, 2002PS27

Study information

Scientific Title

Acronym

BELLS

Study objectives

1. To describe the resolution of neurological deficit and cosmetic, psychological and functional recovery in each of four groups of patients: those treated with prednisolone, aciclovir, both, or neither.
2. To determine which group of patients have the greatest reduction in neurological disability scores on the House and Brackmann grading system at 3 and 9 months after randomisation.
3. To compare self-reported health status (including assessments of pain) at 3 and 9 months after randomisation.
4. To compare the incremental cost per neurological deficit resolved and incremental cost per QALY in the study groups

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design

2 x 2 randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Patient information can be found at: http://www.dundee.ac.uk/bells/sbps_files/sbps_pis_a4_nul.rtf

Health condition(s) or problem(s) studied

Bell's Palsy

Interventions

Design is 2x2 Randomised Controlled Trial (RCT), the 4 arms being:

1. Prednisolone and placebo
2. Aciclovir and placebo
3. Prednisolone and aciclovir
4. Placebo and placebo

Dosage as follows: prednisolone 50 mg/day x 10 days, aciclovir 2000 mg/day x 10 days, lactose placebo indistinguishable.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

prednisolone, aciclovir

Primary outcome measure

1. House-Brackmann grading system for facial nerve function
2. Health Utilities Index
3. Chronic pain grade
4. Costs

Secondary outcome measures

1. Brief Pain Inventory
2. Derriford Appearance Questionnaire (DAS59)

Overall study start date

01/11/2003

Completion date

30/06/2007

Eligibility

Key inclusion criteria

Adults (16 or older) diagnosed with Bell's Palsy and with no excluding conditions and who can be consented at participating centres in Scotland within 72 hours of onset.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Key exclusion criteria

1. Pregnancy
2. Uncontrolled diabetes (HbA1c >8%)
3. Peptic ulcer disease
4. Suppurative otitis media
5. Herpes zoster
6. Multiple sclerosis
7. Sarcoidosis and other rarer conditions
8. Inability to give informed consent
9. Breast-feeding
10. Patients with systemic infection

Date of first enrolment

01/11/2003

Date of final enrolment

30/06/2007

Locations**Countries of recruitment**

Scotland

United Kingdom

Study participating centre

Tayside Centre for General Practice

Dundee

United Kingdom

DD2 4BF

Sponsor information**Organisation**

University of Dundee (UK)

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/03h2bxq36>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/10/2007		Yes	No
Results article	results	01/10/2009		Yes	No