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

Submission date	Recruitment status	[_] Prospectively registered
10/08/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/08/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/10/2009	Nervous System Diseases	

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

720

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
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DD2 4BF

Sponsor information

Organisation
University of Dundee (UK)

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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