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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
10/08/2004		☐ 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

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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 \times 10 days, aciclovir 2000 mg/day \times 10 days, lactose placebo indistinguishable.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

prednisolone, aciclovir

Primary outcome(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

Scotland

Study participating centre
Tayside Centre for General Practice
Dundee
United Kingdom
DD2 4BF

Sponsor information

Organisation

University of Dundee (UK)

ROR

https://ror.org/03h2bxq36

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

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

Participant information sheetParticipant information sheet11/11/202511/11/2025NoYesStudy website11/11/202511/11/2025NoYes