Wessex epidural steroids trial (WEST)

Submission date [] Prospectively registered Recruitment status 25/04/2003 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 25/04/2003 Completed [X] Results [] Individual participant data Last Edited Condition category 08/11/2022 Musculoskeletal Diseases

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Peter Rogers

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 96/31/05

Study information

Scientific Title

Wessex epidural steroids trial (WEST)

Acronym

WEST

Study objectives

The proposed study is a pragmatic multi-centre randomised double blind placebo controlled trial examining the safety and efficacy of epidural steroids in the management of sciatica. It will compare a combination of steroid and local anaesthetic epidural injection with a placebo injection. 120 patients are required in each arm. The study will collect data on functional improvement, pain, physical signs, analgesic intake and impact on global function and mood over one year. A formal cost-effectiveness analysis will be performed. All complications will also be collected.

The objectives are to establish the efficacy and cost-effectiveness of epidural steroids as currently used and identify those who will most benefit.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design

Pragmatic multi-centre randomised double blind placebo controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Musculoskeletal diseases: Spinal conditions

Interventions

- 1. A combination of steroid and local anaesthetic epidural injection
- 2. Placebo injection

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

steroid and local anaesthetic epidural

Primary outcome measure

Functional improvement, pain, physical signs, analgesic intake and impact on global function and mood over one year. A formal cost-effectiveness analysis will also be performed.

Secondary outcome measures

Not provided at time of registration.

Overall study start date

01/01/1999

Completion date

31/03/2002

Eligibility

Key inclusion criteria

240 patients with sciatica

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

240

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/01/1999

Date of final enrolment

31/03/2002

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Anaesthesia
Portsmouth
United Kingdom
PO3 3LY

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House Quarry Hill Leeds United Kingdom LS2 7UE +44 (0)1132 545 843 Sheila.Greener@doh.gsi.gov.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/en/index.htm

ROR

https://ror.org/03sbpja79

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

Not provided at time of registration

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	HTA monograph	01/08/2005		Yes	No