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

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Contact details

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Additional identifiers

Protocol serial number HTA 96/31/05

Study information

Scientific Title

Wessex epidural steroids trial (WEST)

Acronym

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

Study type(s)

Not Specified

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(s)

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.

Key secondary outcome(s))

Not provided at time of registration.

Completion date

31/03/2002

Eligibility

Key inclusion criteria

240 patients with sciatica

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre Department of Anaesthesia

Portsmouth United Kingdom PO3 3LY

Sponsor information

Organisation

Department of Health (UK)

ROR

https://ror.org/03sbpja79

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

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