

Does early imaging influence management and improve outcome in patients with low back pain?

Submission date

25/04/2003

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

25/04/2003

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

27/08/2009

Condition category

Musculoskeletal Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.abdn.ac.uk/hsru/hta/sbt.shtml>

Contact information

Type(s)

Scientific

Contact name

Prof Fiona Gilbert

Contact details

Academic Department of Radiology

University of Aberdeen

Foresterhill Annex

Foresterhill

Aberdeen

United Kingdom

AB9 2ZD

+44 01224 559718

f.j.gilbert@abdn.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 93/17/43

Study information

Scientific Title

Study objectives

For many patients with back pain the optimal role and timing of imaging (lumbar spine radiography, magnetic resonance imaging, computed tomography, myelography) is unclear. The objectives of proposed study are (a) to determine whether early as opposed to delayed selective imaging significantly impacts on clinical management and patient outcome, and (b) to assess the resource implications of the two policies within a formal economic analysis. The application is for a Scottish-based, four-centred trial involving 1200 patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design

Randomised 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. Early imaging
2. Delayed, selective imaging (that is, only when a clear clinical indication develops and only when judged absolutely necessary by the clinician)
A minimisation algorithm will be used to balance the 'random' allocation in respect of key prognostic variables.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The principle measures of patient outcome will be the Oswestry Disability Index and the SF 36 health status measure. Secondary measures will assess diagnostic impact, therapeutic impact and other parameters of health. Follow-up assessments will be performed at 6 and 24 months after entry. Secondary stratified analyses will explore the effects of pre-referral lumbar spine radiographs, amongst other factors.

Secondary outcome measures

Not provided at time of registration.

Overall study start date

01/09/1996

Completion date

31/08/2001

Eligibility**Key inclusion criteria**

Back pain patients referred to a consultant orthopaedic surgeon or neurosurgeon where there is clinical uncertainty about whether or when to perform imaging

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

782

Key exclusion criteria

Patients going for immediate surgery or discharged to primary care would not be eligible.

Date of first enrolment

01/09/1996

Date of final enrolment

31/08/2001

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre

Academic Department of Radiology

Aberdeen

United Kingdom

AB9 2ZD

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

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	01/05/2004		Yes	No