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

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
27/08/2009

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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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
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Sponsor information

Organisation
Department of Health (UK)

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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