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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

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Not Specified

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(s)
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.

Key secondary outcome(s))

Not provided at time of registration.

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

Scotland

Study participating centre
Academic Department of Radiology
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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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes