ISRCTN67513618 https://doi.org/10.1186/ISRCTN67513618

RISCS Trial – Risks In Spinal Consenting for Surgery: Establishing the information required to enable informed consent for patients receiving spinal injections

Submission date
22/03/2017

Recruitment status
No longer recruiting

Registration date
02/10/2017

Overall study status
Completed

Last Edited
29/10/2019

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Informed consent has been established for ethical, medical and legal reasons. Ethically, it is better for the patient and the surgeon to have a shared decision regarding the choice to proceed to an operation. Medically, a patient should be aware of the potential immediate, early and late health outcomes after an operation, and the risks involved. Legally, consent is required to enable fair consideration of liability should complications arise or patient expectations not be met.The legal aspect underpinning informed consent can be viewed as risk management against a potential law suit should problems arise. Based on this view, if the goal of informed consent is simply risk-management, then consent forms should be encyclopaedic, informing the patient of every conceivable risk associated with the surgery. This is not currently true, due to the balance that has to be struck between the ethical aims of the informed consenting process and the potential negative consequences of overloading patients with information. There is no clear definition of how much information is required for consent to be sufficiently informed. Commonly it is loosely defined by what a reasonable person would need to make an appropriate decision. This is subjective, and thus provides sufficient greyness that can be sometimes exploited by legal prosecution teams on behalf of naturally dissatisfied patients. Despite the legal stance, patients frequently report that they do not want to be overburdened with information about very rare risks, and that this information makes them more anxious about their procedure. Increased anxiety before a procedure has been shown to correlate with worse outcomes afterwards, so it could be argued that the legal premise of listing and explaining every single known risk, however rare, could actually be harmful. This study aims to assess if explaining more risks to patients before receiving a spinal injection leads to more patients withdrawing consent due to concerns about those risks.

Who can participate?
Adults aged 18 and older who require a spinal injection.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the standard practice consent form. Those in the second group receive a consent form based on the stance of the legal profession with an encyclopaedic level of risks on the consent form based on literature reports. The amount of participants who withdraw from consenting to the study is recorded and participants have their anxiety status and anxiety traits assessed.

What are the possible benefits and risks of participating?
Participants may benefit by having more information about their procedure and by helping to inform future consenting practices both related to spinal injections and in general. There are no notable risks with participating however participants may feel an increase in anxiety levels. Any patients found to be very anxious will be offered referral to their general practitioner for on-going management of this.

Where is the study run from?
Musgrove Park Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2015 to April 2018

Who is funding the study?
Bristol Orthopaedic Trust (UK)

Who is the main contact?
Mr Paul Thorpe
paul.thorpe@tst.nhs.uk

Study website
https://sites.google.com/view/riscs

Contact information

Type(s)
Public

Contact name
Mr James Fletcher

ORCID ID
http://orcid.org/0000-0003-4147-5013

Contact details
Taunton & Somerset NHS Foundation Trust
Parkfield Drive
Taunton
United Kingdom
TA1 5DA

Type(s)
Public

Contact name
Mr Paul Thorpe

Contact details
Taunton & Somerset NHS Foundation Trust
Parkfield drive
Taunton
United Kingdom
TA1 5DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0.7

Study information

Scientific Title
Risks In Spinal Consenting for Surgery Trial: Randomised, controlled trial comparing standard consenting vs. consenting with all known procedural risks for patient undergoing day case spinal injections based on rates of consent withdraw

Acronym
RISCS

Study objectives
Null Hypothesis:
There will be no reduction in the rate of consenting (i.e. everyone still consents) despite being told of several more risks associated with the procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Health Research Authority: Research Ethics Committee, 16/01/2017, ref: 16/SC/0510

Study design
Single centre interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Consenting practice for spinal injections

Interventions
The study is a non-inferiority, randomised, controlled trial. Two different consent forms to consent patients for their spinal injections are used. One form is the standard practice, based on the risks that are recommended to be discussed by the medical profession, in this instance the British Association of Spinal Surgeons based on the complications listed on the British Spinal Register. The intervention consent form is based on the stance of the legal profession with an encyclopaedic level of risks on the consent form based on literature reports. The only difference to routine practice is the change of consent form in the intervention group and the use of STAI questionnaires in both groups. The duration of treatment is as per patients' current treatment, with follow up to six weeks post operatively; again, this is six weeks post operative follow up is currently routine practice.

Participants are randomised between groups when their trial packs are distributed. The packs contain the different consent forms and have being ordered randomly; these are distributed sequentially.

Intervention Type
Behavioural

Primary outcome measure
Number of patients withdrawing consent for injections is measured using the patient records at time of injection.

Secondary outcome measures
State of anxiety is measured using state-trait anxiety inventory (STAI) scores at time of reading consent form and day of surgery.

Overall study start date
01/11/2015

Completion date
01/11/2018

Eligibility

Key inclusion criteria

1. Spinal injection (facet injection, nerve root or caudal/foraminal injection)
2. Day case, elective patient
3. Able to consent (capacity)
4. Age 18 years or older

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
220

Key exclusion criteria
1. Patients listed for inpatient procedure
2. Emergency injections
3. Patients who are unable to understand English will be excluded because the questionnaires in this study has not been translated and validated into all other languages.
4. Patients who lose capacity before they receive their injection

Date of first enrolment
01/05/2017

Date of final enrolment
31/03/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Musgrove Park Hospital
Taunton & Somerset NHS Foundation Trust
Parkfield Drive
Taunton
United Kingdom
TA15DA

Sponsor information

Organisation
Taunton & Somerset NHS Foundation Trust

Sponsor details
Parkfield Drive
Taunton
England
United Kingdom
TA1 5DA
+44 1823 333444
research@tst.nhs.uk

Sponsor type
Hospital/treatment centre

Website
www.tsft.nhs.uk

ROR
https://ror.org/02y5f7327

Funder(s)

Funder type
Charity

Funder Name
Bristol Orthopaedic Trust

Results and Publications

Publication and dissemination plan
Presentation of the findings is scheduled for National Spinal Surgeon conferences (e.g. BritSpine) and planned publication in a high-impact peer reviewed journal, with publication scheduled around one year after the trial has ended. No documents will be available online. An overview is provided on the trial website https://sites.google.com/view/riscs/home

Intention to publish date
01/04/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository- the RISCS trial data repository. The data stored are patient identifies, whether consent was withdrawn, STAI trait and state questionnaire scores. There is no weblink. The data is accessed by trial team members, all clinicians. The data is stored for one year after the trial has ended. Patients all sign a consent form consenting to their data being stored on the repository. Patient names are removed, but patient identifiers such as date of birth and hospital number are entered alongside their trial number. There are standard legal restrictions as per NHS patient confidential data.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/09/2018	29/10/2019	Yes	No
HRA research summary			26/07/2023	No	No