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The ACL SNNAP Trial: ACL surgery necessity in non acute patients

Submission date
02/11/2016

Recruitment status
No longer recruiting

Registration date
16/11/2016

Overall study status
Completed

Last Edited
01/07/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The anterior cruciate ligament (ACL) is a tough band of tissue in the middle of the knee, preventing the shin bone (tibia) from sliding out in front of the thigh bone (femur). It is one of the four main ligaments within the knee, and the most common to be injured. An ACL rupture is a common knee injury, which often occurs during high-intensity sports such as football or basketball. They happen when the ACL in the knee is over-stretched and becomes torn (ruptured). This causes the knee joint to become very unstable and can make some types of movement very difficult. There are two main NHS treatment options for this problem, non-surgical treatment using physiotherapy or an operation to replace the ligament (ACL reconstruction). This lack of research means that treatment varies between surgeons and hospitals. Some doctors feel that all patients should undergo surgery and as soon as possible to stabilise the joint, prevent buckling and stop any further damage. At least 13,941 of these operations were performed in the UK last year (although other records suggest a figure closer to 50,000). The costs of ACL surgery to the NHS amount to about £60 million per year. Others feel that blanket referral for operative treatment is controversial as surgery may not always be necessary. It is known that a stable knee can be achieved in many patients by using physiotherapy exercises. Some therefore feel that a rehabilitation programme should always be tried first before considering surgery. The aim of this study is to determine the best treatment for ACL rupture.

Who can participate?
Adults who injured themselves at least four months ago who have an ACL rupture.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive regular physiotherapy sessions under the care of clinicians who specialise in this injury. The sessions work on improving the strength of leg muscles, balance and ability to return to activities. Those in the second group undergo ACL reconstruction surgery. This involves an operation where the torn ligament is replaced with a graft (tissue taken from a tendon in another part of the knee). In both groups, the treatments provided are the standard treatments offered at that particular hospital. All patients participating in this study attend follow up visits and are monitored at their local hospital as they would normally following physiotherapy or

surgery. If any problems are experienced a re-view appointment is arranged with the clinical team to discuss future management. If further treatment is needed, this is also arranged. Participants are asked to complete an email or paper follow up questionnaire at 6, 12 and 18 months afterward. The questionnaires ask for information about their injured knee and the associated impact of this on quality of life. Patients may also be contacted by one of our researchers and invited to discuss their experiences of the treatment.

What are the possible benefits and risks of participating?
There are no direct benefits of participating however the information gained from participation could lead to improving future treatments for patients with ACL injury. There are no anticipated risks or disadvantages to participating in this study.

Where is the study run from?
At least 15 NHS hospitals in England and Wales (UK)

When is the study starting and how long is it expected to run for?
January 2014 to September 2021 (updated 05/05/2021, previously: April 2021)

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Professor David Beard (scientific)
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2. Loretta Davis (public)
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(updated 03/01/2020, previously: Mr Carlos Areia)

Study website
https://snnap.octru.ox.ac.uk/

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number
Nil known

ClinicalTrials.gov number
NCT02980367

Secondary identifying numbers
CPMS 31501

Study information

Scientific Title
Comparison of the clinical and cost effectiveness of two management strategies for non-acute Anterior Cruciate Ligament (ACL) injury: Rehabilitation versus surgical Reconstruction

Acronym
ACL SNNAP

Study objectives
The aim of this study is to determine in patients with non-acute (greater than 4 months since injury) Anterior Cruciate Ligament Deficiency (ACLD) whether a strategy of non-surgical management [physiotherapy rehabilitation with option for later ACL reconstruction only if required) is more clinically effective and cost effective than a strategy of surgical management (reconstruction).

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central – Oxford C Research Ethics Committee, 12/10/2016, ref: 16/SC/0502

Study design
Randomized; Interventional; Design type: Treatment, Process of Care, Education or Self-Management, Complex Intervention, Physical, Management of Care, Surgery, Rehabilitation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Specialty: Musculoskeletal disorders, Primary sub-specialty: Elective orthopaedic surgery; UKCRC code/ Disease: Musculoskeletal/ Other disorders of the musculoskeletal system and connective tissue

Interventions
Both interventions are routine NHS treatments. Intervention content is based on a minimal set of pre-established criteria in order to ensure the integrity of the comparison while allowing for varying in practice in delivering the interventions between both surgeons and physiotherapists. This largely pragmatic approach will allow clinical management to reflect current practice and resource use within the NHS thus aiding generalisation. Participants will be allocated a study number and randomised on a 1:1 basis to receive one of two management options, non-surgical management (Rehabilitation) or surgery (Reconstruction). Randomisation will be performed using a web based automated computer generated system and will be stratified by site and baseline KOOS(4) to ensure balance across groups.

Non-surgical management (Rehabilitation): Routine ACL rehabilitation protocols used at participating sites will be followed. As part of the site selection process, documentary evidence of the use of or willingness to adopt a rehabilitation protocol that reflects the guidelines of the mandatory aims/goals set for the study rehabilitation intervention will be required.

Surgical Management (Reconstruction): All surgical reconstructions will be patella tendon or hamstrings tendon depending on the surgeon’s preference. All other care will be routine, including immediate post-operative care.

Other than the allocated intervention, both groups will be followed-up in the same way to exclude bias. Follow up for study purposes will be by patient self-reported questionnaire completed using an electronic data capture collection system (a postal option will also be available). The questionnaire will include the outcomes indicated in section 4 and will be completed by participants at baseline, 6, 12 and 18 months. Non-response will be minimised through use of multiple reminders such as web based, phone and text.

Intervention Type
Other

Primary outcome measure
Knee injury and Osteoarthritis Outcome Score (KOOS4) is meaured at at baseline, 6, 12 and 18 months.

Secondary outcome measures
1. Return to activity/level of sports is measured by the Modified Tegner scale at baseline and 6, 12 and 18 months
2. Generic quality of life is measured using EuroQol EQ-5D at baseline and 6, 12 and 18 months
3. Knee specific quality of life is measured using the KOOS (all subscales, the fifth scale being activities of daily living) and Anterior Cruciate Ligament Quality of Life score (ACL-QOL) at baseline and 6, 12 and 18 months
4. Intervention related complications is determined as any complications associated with undergoing ACL deficiency treatment*, recorded at 6, 12 and 18 months
5. Resource usage data on initial treatments received and subsequent healthcare costs such as re-operations, subsequent surgical reconstructions, surgery related complications, further rehabilitation, and primary and other secondary care contacts, ability to work (e.g. sickness absences/return to work number of days off work and subjective working ability) is collected at baseline and 6, 12 and 18 months
6. Expectations of return to activity and confidence in relation to the knee is measured by the Anterior Cruciate Ligament Quality of Life score (ACL-QOL) at baseline and 6, 12 and 18 months
7. Patient satisfaction with the outcome of treatment is measured using a simple Likert scale at 6, 12 and 18 months

*This includes; for surgery group; re-admission, delayed hospital discharge, infection, unexpected poor range of movement (stiffness), excess bleeding, continued swelling, episodes of giving way, continued feeling of instability. For non-surgical group; continued swelling, episodes of giving way.

Overall study start date
10/01/2014

Completion date
11/09/2021

Eligibility

Key inclusion criteria

1. Participant is willing and able to give informed consent for participation in the study
2. Male or Female, aged 18 years or above
3. Symptomatic ACL deficiency (instability-episodes of frank giving way or feeling unstable) with ACL deficiency confirmed using clinical assessment and MRI scan

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 320; UK Sample Size: 320

Total final enrolment
316

Key exclusion criteria
1. Less than 4 months since injury
2. Previous knee surgery (other than diagnostic arthroscopy)to index knee, concomitant severe injury to contra-lateral knee
3. Meniscal pathology considered sufficiently symptomatic to require surgery i.e. locked knee, large bucket handle cartilage tear
4. Knee joint status is grade 3-4 on the Kellgren and Lawrence scale
5. Inflammatory arthropathy
6. Grade 3 MCL/LCL injury, associated PCL/PLC injury
7. Pregnancy

Date of first enrolment
01/12/2016

Date of final enrolment
11/03/2020

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Nuffield Orthopaedic Centre NHS Trust
Oxford University Hospitals NHS Foundation Trust
Windmill Road
Headington
Oxford
United Kingdom
OX3 7LD

Study participating centre
Royal Berkshire Hospital
Royal Berkshire NHS Foundation Trust
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
King's Mill Hospital
Sherwood Forest Hospitals NHS Foundation Trust
Mansfield Road
Sutton-in-Ashfield
United Kingdom
NG17 4JL

Study participating centre
University Hospital of Wales
Cardiff and Vale NHS Trust
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Great Western Hospital
Great Western Hospitals NHS Foundation Trust
Marlborough Road
Swindon
United Kingdom
SN3 6BB

Study participating centre
Yeovil District Hospital
Yeovil District Hospital NHS Foundation Trust
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

Study participating centre
Ipswich Hospital
Ipswich Hospital NHS Trust
Heath Road
Ipswich
United Kingdom
IP4 5PD

Study participating centre
University College London Hospital
London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Leicester General Hospital
University Hospitals of Leicester NHS Trust
Gwendolen House
Gwendolen Road
Leicester
United Kingdom
LE5 4QF

Study participating centre
Hull Royal Infirmary
Hull and East Yorkshire Hospitals NHS Trust
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
Queen Alexandra Hospital
Portsmouth Hospitals NHS Trust
Southwick Hill Road
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Frimley Park Hospital
Frimley Park Hospitals NHS Foundation Trust
Portsmouth Road
Frimley
United Kingdom
GU16 7UJ

Study participating centre
Morriston Hospital
Abertawe Bro Morgannwg University Health Board
Morriston
Heol Maes Eglwys
Swansea
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SA6 6NL

Study participating centre
Northern General Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
University Hospital Coventry
University Hospitals Coventry and Warwickshire NHS Trust
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CV2 2DX

Sponsor information

Organisation
University of Oxford

Sponsor details
Clinical Trials and Research Governance
Joint Research Office
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Churchill Hospital
Headington
Oxford
England
United Kingdom
OX3 7LE

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Publications will include a final report, as well as presentations at scientific meetings and publication of findings in scientific literature. All will be published in line with NIHR guidance. The trial protocol will be published in 2017 and the main trial results paper in 2021. In addition, all participants in the trial will be sent a summary of the final results written in plain English and details of where to find further information.

Intention to publish date
11/09/2022

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2.0	13/10/2016	16/11/2016	No	Yes
Protocol article	protocol	14/05/2020	18/05/2020	Yes	No
Statistical Analysis Plan		12/05/2022	16/05/2022	No	No
Results article		20/08/2022	22/08/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/06/2024	01/07/2024	Yes	No