

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

Submission date 02/11/2016	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 16/11/2016	Overall study status Completed	☒ Statistical analysis plan ☒ Results
Last Edited 01/07/2024	Condition category Musculoskeletal Diseases	☐ 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)

Contact information

Type(s)

Scientific

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Additional identifiers**ClinicalTrials.gov (NCT)**

NCT02980367

Central Portfolio Management System (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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

Knee injury and Osteoarthritis Outcome Score (KOOS4) is measured at at baseline, 6, 12 and 18 months.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

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
United Kingdom
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
Walsgrave General Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Sponsor information**Organisation**

University of Oxford

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

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?
Results article	protocol	20/08/2022	22/08/2022	Yes	No
Results article		01/06/2024	01/07/2024	Yes	No
Protocol article		14/05/2020	18/05/2020	Yes	No
HRA research summary	version V2.0		28/06/2023	No	No
Participant information sheet		13/10/2016	16/11/2016	No	Yes
Statistical Analysis Plan		12/05/2022	16/05/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes