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How are repeat(ed) steroid injections into osteoarthritic joints used and what are the outcomes?

Submission date
27/03/2020

Recruitment status
No longer recruiting

Registration date
11/08/2021

Overall study status
Completed

Last Edited
18/11/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis is a condition that causes joints to become painful and stiff, it is a common cause of pain and disability. Management of osteoarthritis involves reducing pain and maintaining function. Simple treatments include activity modification, staying active to maintain muscle strength and taking pain medication. Complex treatments include joint replacement (replacing the painful joint with an artificial joint), which may be required for those with pain that cannot be well controlled by other means. Before a joint replacement is considered, it is possible to use other techniques, such as injections into the affected joint, to try to reduce pain. These injections are most commonly used for knee osteoarthritis. The injection usually contains both an anaesthetic to help with the pain and a steroid to reduce the inflammation (swelling, redness, heat and pain) within the joint. It is known that these injections can help with pain if used infrequently and that their use is recommended by a variety of organisations, including the NHS. However, little is known about the effect of using repeated injections.

Who can participate?
For the qualitative interviews: patients who have received intra-articular injections of corticosteroid for osteoarthritis, those who have received recurrent injections, patients with osteoarthritis who have not received injections, clinicians who have experience of prescribing and administering intra-articular injections of corticosteroid and those who have not administered injections.
For the Delphi survey: patients, healthcare professionals involved in the treatment of patients with joint disease, academics and commissioners.

What does the study involve?
The researchers wish to use data that has already been collected on patients treated for osteoarthritis in primary care (by their GP or a physiotherapist) who have or have not received an injection. Using this data, the researchers will look at the current use of injections, the safety of their use, how good they are, and whether they affect other treatments and the timing of these. The researchers will also interview people involved in this treatment (patients and healthcare professionals) to help understand their experience of the treatment, attitudes to its use, how

best it can be used, the acceptability of future research in this area and what are the most important outcomes that should be assessed. The researchers will also invite patients, healthcare professionals and commissioners to take part in questionnaire surveys to find out what the important questions are that need to be answered by any studies in the future, whether it would be possible to do these studies and how they should be conducted.

What are the possible benefits and risks of participating?
None anticipated

Patient and public involvement
The researchers have discussed the study with our patient and public involvement group, the Patient Experience Partnership in Research (PEP-R) group, an established forum of 8 service users with musculoskeletal conditions. They agreed that it was important to look at the results of treatment with injections for osteoarthritis. Members of the group had the experience of receiving injections for osteoarthritis and sites including the knee and hand. Some group members had experienced problems with receiving injections as not all the GPs in their practice performed them and some only injected certain joints. They felt that it was important to establish whether injections helped with pain and how safe they were to use, including whether there should be a limit to the number received and over what period of time. They also felt it was very important to look at whether injections led to a delay in other procedures such as joint replacement. The PEP-R group members provide very useful feedback and input for the plain English summary and have offered to provide ongoing support throughout the study.

Where is the study run from?
Southmead Hospital, Bristol (UK)

When is the study starting and how long is it expected to run for?
September 2020 to May 2023

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
281208

Integrated Research Application System (IRAS)
284918

Central Portfolio Management System (CPMS)
46157

Grant Code
NIHR129011

Study information

Scientific Title
RecUrrent Intra-articular Corticosteroid injections in Osteoarthritis; the RUbICOn study

Acronym
RUBICON

Study objectives
The data generated in this study will provide comprehensive and contemporary information on the pattern of use of intra-articular injections of joints for osteoarthritis in primary care. The safety of use and the treatment effect will be assessed as well as the effect of receiving the intervention on the timing of subsequent surgical interventions. Where the subsequent intervention is arthroplasty, the influence of intra-articular injection on the risk of adverse events following arthroplasty and patient-reported pain and function will be assessed. Qualitative interviews will explore the experience and views of patients and clinicians on receiving/administering intra-articular injections. A Delphi consensus exercise will inform future research priorities and the feasibility of carrying out such research.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Routinely collected healthcare data analysis:
Use of anonymised linked healthcare data approved 16/10/2020, Clinical Practice Research Datalink Independent Scientific Advisory Committee, ref: 20_067RA

Qualitative interviews:
Approved 20/07/2020, East Midlands - Leicester Central Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham NG1 6FS; +44 (0)207 104 8388; leicestercentral.rec@hra.nhs.uk), ref: 20/EM/0185

Delphi survey:
Approved 24/05/2021, North of Scotland Research Ethics Service (Summerfield House, 2 Eday Road, Aberdeen AB15 6RE; +44 (0)1224 558458; gram.nosres@nhs.scot), ref: 21/NS/0070

Study design
Retrospective observational study, qualitative interview study, and Delphi consensus survey

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthrosis

Interventions
Routinely collected healthcare data analysis:
Analysis of routinely collected observational healthcare datasets (Clinical Practice Research Datalink, Hospital Episode Statistics and NHS Digital Patient Reported Outcome Measures) between 01/01/2005 and 20/10/2017 to determine the use, safety and effect of intra-articular

corticosteroid injections for osteoarthritis. Data from patients with osteoarthritis that have received the intervention of interest (intra-articular corticosteroid injections with a dosage and frequency of injection according to the standard of care) will be analysed.

Qualitative interviews:
Qualitative interviews with up to 40 patients and 30 primary care clinicians will be performed to explore their personal views and experiences of receiving and administering intra-articular steroid injections for painful osteoarthritis. Eligible participants will each undergo one semi-structured in-depth interview lasting approximately 60 min for patients and 45 min for clinicians. These will be conducted face-to-face where possible or via telephone or Skype. Interviews with patients will explore their experience of receiving intra-articular steroid injections for osteoarthritis, and the benefits and disadvantages of treatment. Interviews with clinicians will explore their views and experiences of prescribing/administering intra-articular injections, including their beliefs about the efficacy of the injections. Interviews will be audio-recorded and then transcribed and anonymised. Transcripts will be analysed using thematic analysis and healthcare behaviour theories. After the interviews are complete, there will be no further follow-up/contact of the participants.

Delphi survey:
3 rounds of a modified Delphi study of patients, healthcare professionals, researchers, and commissioners to develop expert consensus and identify future primary research priorities and associated feasibility of these recommendations. To ensure the four key stakeholder groups are represented equally, we will recruit 100 participants through established networks: 25 patients, 25 healthcare professionals, 25 academics and 25 commissioners. Round 1 of the survey will identify key research questions and associated feasibility, round 2 will involve ranking each identified research question, and round 3 will involve a final consensus of the retained research questions to provide a final research question priority list. Questions will be included in the final priority list if either they are assigned a high importance rating by 70% or more of all participants, or they are assigned a high importance rating by 90% or more of members from one of the four key stakeholder groups. After the 3 rounds of survey are complete, there will be no further follow-up/contact of the participants.
There will be no deliberate co-enrolment of participants between WP2 and WP3. However identification of patients and clinicians will be coordinated by external bodies (CRN and CCG), thus it is possible that some participants may be invited to participate in both pieces of work.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Intra-articular steroid injections

Primary outcome(s)
Routinely collected healthcare data analysis:
1. Current practice of the joint site (knee, hip, hand, shoulder, ankle/foot, wrist, and elbow) for intra-articular corticosteroid injections measured from Clinical Practice Research Datalink (CPRD) data collected for the period 01/01/2005 to 20/10/2017
2. Incidence and prevalence of use of intra-articular corticosteroid injections measured from CPRD data collected for the period 01/01/2005 to 20/10/2017

3. Secular trends of use of injections over the overall population calculated from CPRD data collected for the period 01/01/2005 to 20/10/2017
4. Number of repeat injections over time measured from patient-level CPRD data collected for the period 01/01/2005 to 20/10/2017
5. Cumulative use (number of daily defined doses of steroid/s injected in total), and medication possession ratio (number of daily defined doses of steroid injected over the number of days from first to last injection) measured from patient-level CPRD data collected for the period 01/01/2005 to 20/10/2017

Qualitative interviews:
Views and experiences of receiving and administering intra-articular steroid injections for painful osteoarthritis assessed using healthcare behaviour theory informed analysis of the transcripts of semi-structured in-depth interviews with patients and primary care clinicians at a single interview

Delphi survey:
Future primary research priorities and associated feasibility assessed using a Delphi survey of patients, healthcare professionals, researchers, and commissioners over 3 rounds

Key secondary outcome(s))

Routinely collected healthcare data analysis:
1. Safety:
1.1. Use of post-operative (joint replacement surgery) analgesia (up to 1-year) including paracetamol (acetaminophen), topical & parenteral NSAIDs, opioid analgesia and/or use of gabapentinoids and anti-epileptic drugs measured from CPRD data collected for the period 01/01/2005 to 20/10/2017:
1.1.1. Number of medication prescriptions
1.1.2. Daily defined doses (DDD) of different types of analgesia (NSAID, opioids) received following the Index Prescription
1.2. Post-intra-articular injection and post-operative (joint replacement surgery) bleeding (up to 6-months) measured from CPRD data collected for the period 01/01/2005 to 20/10/2017
1.3. Post-intra-articular injection and post-operative (joint replacement surgery) infection (up to 6-months) measured from CPRD data collected for the period 01/01/2005 to 20/10/2017
1.4. Post-intra-articular injection and post-operative (joint replacement surgery) diabetes decompensation (up to 6-months) measured from Clinical Practice Research Datalink (CPRD) and Hospital Episode Statistics (HES) data collected for the period 01/01/2005 to 20/10/2017
1.5. Post-intra-articular injection and post-operative (joint replacement surgery) cardiovascular events (up to 6-months) measured from CPRD and HES data collected for the period 01/01/2005 to 20/10/2017
1.6. Mortality (up to 6-months) measured from CPRD and HES data collected for the period 01/01/2005 to 20/10/2017
2. Use of post-intra-articular injection and post-operative (joint replacement surgery) steroid injections (up to 1-year) measured from CPRD data collected for the period 01/01/2005 to 20/10/2017
3. Use of post-intra-articular injection and post-operative (joint replacement surgery) oral corticosteroids (up to 1-year) measured from CPRD data collected for the period 01/01/2005 to 20/10/2017
4. Time to intermediate surgical interventions post-intra-articular injection including joint injections (up to 10-years), hip and knee arthroscopy (up to 10-years), meniscal debridement (up to 10-years), joint washout (up to 10-years), ACL reconstruction (up to 10-years), joint arthroplasty (up to 10-years) measured from CPRD and HES data collected for the period 01/01/2005 to 20/10/2017

For participants that receive hip and knee arthroplasty:
1. Joint infection (Wound infection, Pneumonia, Urinary tract infection, Wound dehiscence (up to 6-months) measured from CPRD and HES data collected for the period 01/01/2005 to 20/10/2017
2. Further surgery to the same joint (e.g. debridement, manipulation under anaesthetic, revision, or hip dislocation) (up to 10-years) measured from CPRD and HES data collected for the period 01/01/2005 to 20/10/2017
3. Readmission due to thrombosis, myocardial infarction, and stroke (up to 6-months) measured from HES data collected for the period 01/01/2005 to 20/10/2017
4. Quality of life, function, and pain measured using Oxford Hip Score, Oxford Knee Score, and EQ5D (up to 6-months) from Hospital Episode Statistics and NHS Digital Patient Reported Outcome Measures data collected for the period 01/01/2005 to 20/10/2017

Completion date
31/05/2023

Eligibility

Key inclusion criteria
Qualitative interviews:
1. Patients who have received intra-articular injections of corticosteroid for osteoarthritis
2. Received recurrent injections
3. Patients with osteoarthritis who have not received injections
4. Clinicians who have experience of prescribing and administering intra-articular injections of corticosteroid and those who have not administered injections.

Delphi survey:
1. Patients, healthcare professionals involved in the treatment of patients with joint disease, academics and commissioners

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
148

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment

01/01/2021

Date of final enrolment
01/03/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR CRN West of England
Whitefriars
Lewins Mead
Bristol
England
BS1 2NT

Study participating centre
University of Bristol Musculoskeletal Research Unit
Learning and Research Building (Level 1)
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BS10 5NB

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

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
Data will be stored in the University of Bristol Research Data Repository and accessible to bona fide researchers via application to the University of Bristol Data Access Committee for WP2 and WP3 (qualitative interviews and Delphi survey)

The ISAC approval for analysis of the Clinical Practice Research Datalink and linked data will not allow public sharing of the raw data for WP1 (routinely collected healthcare data analysis) but researchers can request access to the data through the same ISAC process that was used for this study, this data access is subject to a fee that is levied by CPRD.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/11/2025	18/11/2025	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			26/07/2023	No	No
Participant information sheet	for clinicians for qualitative interviews version 1.1	11/08/2020	11/08/2021	No	Yes
Participant information sheet	for clinicians, commissioners, and academics for Delphi survey version 1	01/04/2021	11/08/2021	No	Yes
Participant information sheet	for patients for Delphi survey version 2	21/05/2021	11/08/2021	No	Yes

Participant information sheet	for patients for qualitative interviews version 1.2	15/02/2021	11/08/2021	No	Yes
Participant information sheet	for primary care staff for Delphi survey version 1	01/04/2021	11/08/2021	No	Yes
Protocol file	version 1.0	12/06/2020	11/08/2021	No	No
Protocol file	Delphi survey protocol version 1	01/04/2021	11/08/2021	No	No
Study website		11/11/2025	11/11/2025	No	Yes