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Precision medicine and personalized care in patients with rotator cuff disease: future perspectives and new frontiers using machine learning models

Submission date
16/10/2023

Recruitment status
Recruiting

Registration date
24/11/2023

Overall study status
Ongoing

Last Edited
08/05/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Rotator cuff (RC) tear is one of the most common shoulder injuries that causes pain and severe limitations in performing activities of daily living. Surgical procedures represent the best treatment option in patients with symptomatic RC tears and severe dysfunction of shoulder movement but the risk of retear remains a major postoperative drawback. The incidence of retear is influenced by biological, genetic and biomechanical factors. In the last years, machine learning has been a tool of strong interest in clinical medicine. In the orthopedics field, little discussion has revolved around how to apply these tools for the early prediction of surgical treatments and personalized care of RC patients.
The aim of the study is to create a pre- and post-operative database with clinical, structural, genetic, and kinematic data from RC patients. In addition, by developing a new machine learning model, pre-operative data will be able to predict clinical and structural outcomes, suggesting new insights for treatment of RC tears.

Who can participate?
Patients aged 40-75 years at Fondazione Policlinico Universitario Campus Bio-Medico with rotator cuff tears

What does the study involve?
An experienced orthopedic surgeon will perform surgical procedures on all patients. Patients will undergo pre- and post-surgical (12-month) follow-up visits which will include assessments, MRI scans, and blood and tissue samples taken during surgery for genetic analysis. The total duration of the study is 48 months.

What are the possible benefits and risks of participating?
There are no risks for the patients recruited in the study.

Where is the study run from?
Fondazione Policlinico Universitario Campus Bio-Medico (Italy)

When is the study starting and how long is it expected to run for?
January 2023 to January 2027

Who is funding the study?
PNRR (National Recovery and Resilience Plan): M6/C2_CALL 2022. This research was supported by EU funding within the NextGenerationEU - Italian Ministry of Health PNRR (Project no. PNRR-MAD-2022-12376080) - CUP: F83C22002450001

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title

A multimodal machine learning approach for precision medicine and personalized care of patients with rotator cuff diseases

Acronym
PREDICT-CUFF

Study objectives
The main hypothesis is that preoperative data can predict clinical and structural outcomes by defining new reliable features, which in turn may suggest new insights for rotator cuff (RC) tear treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 30/01/2023, Comitato Etico Fondazione Policlinico Universitario Campus Bio-Medico (Via Álvaro del Portillo, 21, Roma, 00128, Italy; +39 (0)6225418812; comitato.etico@policlinicocampus.it), ref: PAR 04.23

2. Approved 30/05/2023, Comitato Etico Fondazione Policlinico Universitario Campus Bio-Medico (Via Álvaro del Portillo, 21, Roma, 00128, Italy; +39 (0)6225418812; comitato.etico@policlinicocampus.it), ref: 001.23(04.23)

Study design
Interventional prospective monocentric study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life, Efficacy

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
Rotator cuff tears

Interventions
An experienced orthopedic surgeon will perform surgical procedures on all the enrolled patients after obtaining consent for the study participation. The arthroscopic RC repair will be performed by placing one row of double-loaded suture anchors. Enrolled patients will undergo pre- and post-surgical (12 months) follow-up visits during which the staff in charge will perform clinical-

functional assessments, administration of clinical scores, MRI evaluation, and kinematic analysis using a stereophotogrammetric system. In addition, blood and tissue samples required for subsequent genetic analysis will be taken during surgery.

Intervention Type
Mixed

Primary outcome measure
Structural tendon integrity, as evidenced by MRI evaluations at 12 months after surgery

Secondary outcome measures
Measured before and after surgery:
1. Kinematic variables (such as range of motion, angular velocity) measured by kinematic analysis
2. Physical and subjective measures of the affected shoulder in terms of pain, activities of daily living (ADL), range of motion (ROM), and strength measured by the Constant-Murley score (CMS)
3. Patient self-reported and clinician scores about pain, ADL, ROM, signs, strength, and instability measured by the American Shoulder and Elbow Surgeons (ASES) score
4. Quality of life and mental health (such as physical and social functioning, general health perception limitations due to emotional aspects, vitality) measured by SF-36
5. The level of pain perceived by patients measured by visual analogue score (VAS)

Overall study start date
01/01/2023

Completion date
31/01/2027

Eligibility

Key inclusion criteria
1. Age 40-75 years
2. Rotator cuff tears documented with MRI
3. No surgical treatment to the affected shoulder before
4. No episodes of shoulder instability
5. No radiographic signs of fracture of the glenoid fossa or the greater or lesser tuberosity

Participant type(s)
Patient

Age group
Mixed

Lower age limit
40 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Frozen shoulder
2. Radiological osteoarthritis of the glenohumeral joint
3. Neurological disease or language barriers
4. Impossibility to undergo an MRI scan for any reason

Date of first enrolment
01/01/2024

Date of final enrolment
31/01/2026

Locations

Countries of recruitment
Italy

Study participating centre
Fondazione Policlinico Universitario Campus Bio-Medico
Via Alvaro del Portillo, 200
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Sponsor information

Organisation
Fondazione Policlinico Universitario Campus Bio-Medico

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Sponsor type
Hospital/treatment centre

Website
https://www.policlinicocampusbiomedico.it/

Funder(s)

Funder type
Government

Funder Name
PNRR (National Recovery and Resilience Plan): M6/C2_CALL 2022. This research was supported by EU funding within the NextGenerationEU - Italian Ministry of Health PNRR (Project no. PNRR-MAD-2022-12376080) - CUP: F83C22002450001

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2028

Individual participant data (IPD) sharing plan
Dedicated personnel will develop a centralized web-based database. The e-infrastructure will be managed by authorized and authenticated access by users, who will be able to upload data and view patient information. Specific procedures for anonymity and protection of sensitive subject data will be implemented. In addition, the PI will organize monthly meetings to verify the reliability and accuracy of the collected data.

Patients who meet the inclusion criteria and have expressed an interest in participating will be asked to provide dated and signed informed consent. All participants will be assigned a unique identification code. No information identifying the participant in any way will be disseminated. The database will be anonymized through the use of the unique identification code associated with each subject recruited and managed with appropriate protection systems; demographic data identifying each patient will be stored in a separate spreadsheet available only to the study responsibles or their delegates. The database generated during and/or analyzed during the current study are not expected to be made available due to the sensitivity of patient data.

IPD sharing plan summary
Not expected to be made available