Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Development and evaluation of the effectiveness of an AI-based educational–clinical platform as a "second reader" for Kellgren–Lawrence grading in knee radiography: a randomized controlled trial

Protocol summary

Study aim
Development and evaluation of the effectiveness of an AI-based educational–clinical platform as a “second reader” for Kellgren–Lawrence grading in knee radiography: a randomized controlled trial

Design
Two-arm parallel-group randomized controlled trial, single-center, individual randomization, 1:1 allocation, multi-reader multi-case design, with pretest and posttest

Settings and conduct
This randomized clinical trial evaluates the diagnostic performance and accuracy of a deep learning (AI) algorithm in grading knee osteoarthritis using Kellgren-Lawrence (KL) criteria, comparing AI-assisted interpretations against human readers using standard digital knee radiographs.

Participants/Inclusion and exclusion criteria
Eligible participants are interns and residents of orthopedics, physical medicine and rehabilitation, and radiology in training years 1–3, without prior structured training or substantial experience in Kellgren–Lawrence grading or AI-based diagnostic support systems. Inclusion criteria include written informed consent, stable internet and computer access, and ability to complete the pretest and posttest within the study period. Exclusion criteria include incomplete pretest or posttest, failure to receive the minimum educational dose, withdrawal of consent, or any technical/operational issue preventing study completion

Intervention groups
Standard education plus an AI-based educational–clinical “second reader” platform providing Kellgren–Lawrence grading, confidence estimation, and explainable heatmap feedback; the control group receives standard education without AI output

Main outcome variables
Diagnostic accuracy of deep learning algorithm for Kellgren-Lawrence grading of knee osteoarthritis Inter-observer agreement (Cohen's kappa) between AI predictions and expert radiologist readings

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230723058893N4**
Registration date: **2026-08-31, 1405/06/09**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-31, 1405/06/09**
Update count: **0**

Registration date
2026-08-31, 1405/06/09

Registrant information

Name
Sahar Bagheri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3336 6552

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dr_sbagheri@yahoo.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-23, 1405/06/01

Expected recruitment end date
2026-12-21, 1405/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Development and evaluation of the effectiveness of an AI-based educational–clinical platform as a "second reader" for Kellgren–Lawrence grading in knee radiography: a randomized controlled trial

Public title
Development and evaluation of the effectiveness of an AI-based educational–clinical platform as a "second reader" for Kellgren–Lawrence grading in knee radiography: a randomized controlled trial
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Provision of written informed consent Stable access to the internet and a computer for using the platform No significant prior experience with Kellgren–Lawrence grading or AI-based diagnostic support systems, based on a self-reported screening checklist Ability to complete the pre-test and post-test within the specified timeframe
Exclusion criteria:
Having significant prior experience in KL grading Having significant prior experience working with AI-based computer-aided diagnostic systems.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **280**
More than 1 sample in each individual
Number of samples in each individual: **120**
Each participant evaluates 20 cases in the pre-test, 70–80 cases during the educational intervention, and 20 new cases in the post-test
Randomization (investigator's opinion)
Randomized
Randomization description
Individual participants will be randomized in a 1:1 allocation ratio to either the control group or the intervention group. A variable block randomization method will be used to generate the allocation sequence. Where feasible, randomization will be stratified by educational specialty and baseline skill level to maintain balance between the study groups. Randomization will be performed after completion of the pre-test. Allocation concealment will be maintained until completion of the pre-test, after which the appropriate software access will be assigned according to the participant’s allocated group
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
mam (RA) Teaching and Therapeutic Hospital of Sari - Mazandaran University of Medical Sciences (Res
Street address
No. 3, Ayatollah Salehi Alley, Mir Mashhad Neighborhood, Behind Ibn Ashub Library, Islamic Republic Street, Sari, Mazandaran Province
City
sari
Province
Mazandaran
Postal code
4816646796
Approval date
2026-05-16, 1405/02/26
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1405.028

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Diagnostic accuracy of deep learning algorithm in grading knee osteoarthritis based on Kellgren-Lawrence (KL) criteria
Timepoint
Baseline (immediately upon evaluation of knee radiographs by the AI model and human readers)
Method of measurement
Evaluated by deep learning model and expert radiologists using the Kellgren-Lawrence grading system on standard weight-bearing anteroposterior knee radiographs

Secondary outcomes

1

Description
Diagnostic sensitivity, specificity, and processing time of the deep learning algorithm compared to expert radiologists in detecting knee osteoarthritis
Timepoint
Baseline (immediately upon evaluation of knee radiographs by the AI model and human readers)
Method of measurement
Statistical analysis using Cohen's kappa coefficient to assess inter-observer agreement, and receiver operating characteristic (ROC) curve analysis to evaluate diagnostic performance parameters

Intervention groups

1

Description
Intervention group: Standard digital knee radiographs evaluated using the deep learning (AI) algorithm to grade knee osteoarthritis according to the Kellgren-Lawrence (KL) classification criteria
Category
Diagnosis

2

Description
Control group: Standard training without AI output.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini (RA) Hospital, Sports Medicine Clinic.
Full name of responsible person
Dr. Sahar Bagheri.
Street address
No. 3, Ayatollah Salehi Alley, Mir Mashhad Neighborhood, Behind Ibn Ashub Library, Islamic Republic Street, Sari, Mazandaran Province,
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+98 915 264 8141
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sadathosseini767676@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Professor Ahmad Ali Enayati
Street address
No. —, Maalem Square, Deputy of Research and Technology Building, Sari, Mazandaran Province
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4817844718
Phone
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Email
pajhooheshi@mazums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Elaheh Sadat Hosseini.
Position
Sports Medicine Resident.
Latest degree
Medical doctor
Other areas of specialty/work
Sport Medicine
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No. 3, Ayatollah Salehi Alley, Mir Mashhad Neighborhood, Behind Ibn Ashub Library, Islamic Republic Street, Sari, Mazandaran Province
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Study protocol, statistical analysis plan, and informed consent form: These documents contain the methodology, statistical analysis details, and participant consent procedures for evaluating the AI model's accuracy in knee osteoarthritis grading
When the data will become available and for how long
Starting 6 months after the publication of the study results for a period of up to 5 years
To whom data/document is available
Available to academic researchers and clinicians affiliated with universities or research centers upon reasonable request
Under which criteria data/document could be used
For scientific research, systematic reviews, and meta-analyses related to artificial intelligence applications in knee osteoarthritis grading, subject to approval of the study proposal by the primary investigator
From where data/document is obtainable
Obtainable by submitting a formal request via email to the corresponding author / principal investigator
What processes are involved for a request to access data/document
Applicants must submit a formal request and research proposal to the principal investigator via email. The proposal will be reviewed within 2 to 4 weeks, and upon approval, the documents will be provided
Comments