STUDY PROTOCOL

Prevalence of Overactive Bladder Symptoms and Urinary Incontinence and Their Impact on Quality of Life in Women With Rheumatoid Arthritis: A Multicenter Cross-Sectional Study With Healthy Controls

English protocol and ClinicalTrials.gov registration-ready field summary | Draft version 1.0 | 11 October 2026

Based on the supplied Ege University Medical Research Ethics Committee application (application no. 2025-6619; file no. 25-12.1T/24; application dated 21 December 2025). These identifiers do not establish ethics approval.

1. Protocol synopsis

Study type	Observational (non-interventional)
Design	Multicenter, analytical, cross-sectional, two-cohort comparison
Study population	Women aged 20–60 years with rheumatoid arthritis (RA), and age- and BMI-matched female controls without RA or other chronic inflammatory diseases
Planned enrollment	900 participants: 450 RA, 450 controls
Sampling	Non-probability clinical recruitment; exact sampling approach and matching procedure to be confirmed
Time perspective	Cross-sectional; data gathered at a single study visit
Study duration	180 days (planned); actual start/completion dates to be confirmed
Investigational intervention	None; no allocation, randomization, investigational drug, device, or biological sampling
Core instruments	Overactive Bladder Symptom Score (OABSS), International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form (ICIQ-UI SF), Incontinence Impact Questionnaire–7 (IIQ-7); DAS28 in RA cohort
Principal investigator	Prof. Yeşim Akkoç; Ege University Faculty of Medicine, Department of Physical Medicine and Rehabilitation

2. Background and rationale

Rheumatoid arthritis is a systemic inflammatory disease associated with substantial impairment in physical function and health-related quality of life. Lower urinary tract

symptoms, including urgency, increased daytime frequency, nocturia, and urinary incontinence, have been reported in women with RA. However, published estimates vary and the relationships between urinary symptoms, RA disease activity and symptom-related quality of life remain uncertain. Prior studies have been limited by relatively small samples and, in some cases, the absence of a healthy comparison group. A multicenter study with a substantial control cohort may better characterize the prevalence and severity of urinary symptoms and explore associated clinical factors. The cross-sectional design permits association analyses but not causal inference.

3. Objectives and hypotheses

Primary objective

To compare the prevalence and severity of overactive bladder (OAB) symptoms and urinary incontinence (UI) between women with RA and women without RA or other chronic inflammatory diseases.

Secondary objectives

To assess associations of urinary symptoms with age, body mass index (BMI), menopausal status, parity, smoking, alcohol use and other measured demographic characteristics; to examine associations with RA duration and DAS28 within the RA cohort; and to compare the urinary symptom–related quality-of-life burden between cohorts.

Hypotheses

Women with RA will have a higher prevalence and greater severity of OAB symptoms and UI than healthy controls; higher DAS28 scores will be associated with worse urinary symptoms within the RA cohort; and symptom-related quality-of-life burden will be greater in the RA cohort.

4. Study design and setting

This is a multicenter, observational, analytical, cross-sectional study involving rheumatology and physical medicine and rehabilitation outpatient clinics at participating centers in Türkiye. Each eligible participant will complete one assessment lasting approximately 15–20 minutes. Clinical care will not be altered by study participation. There will be no follow-up visits or prospective treatment assignments. Participating site activation and the final site list will be confirmed by the coordinating team.

5. Study population and eligibility

Rheumatoid arthritis cohort: inclusion criteria

Female sex; age 20–60 years; established RA meeting the 2010 ACR/EULAR classification criteria; ability and willingness to provide written informed consent.

Control cohort: inclusion criteria

Female sex; age 20–60 years; no history of RA or another chronic inflammatory disease; selection to achieve comparability with the RA cohort in age and BMI; ability and willingness to provide written informed consent.

Exclusion criteria (both cohorts)

Active urinary tract infection; neurogenic bladder or a neurological disorder known to cause neurogenic bladder (e.g., multiple sclerosis or Parkinson disease); previous surgery for urinary incontinence; Sjögren syndrome; diagnosed diabetes mellitus; prior pelvic radiotherapy; pregnancy or suspected pregnancy. RA or another chronic inflammatory disease additionally excludes participants from the control cohort.

6. Recruitment, matching and consent

Potentially eligible participants will be approached at participating outpatient clinics. Investigators will explain the study and obtain signed written informed consent before administering study-specific questionnaires. Recruitment will be voluntary and no participant will be randomized. The source specifies that controls will be comparable in age and BMI, but does not define a matching algorithm or tolerance; these operational details should be finalized before registration and analysis, without implying individual pair matching unless it is actually performed.

7. Study procedures and measures

Demographic and clinical variables

Age, BMI, education, occupation, obstetric history and parity, menopausal status, smoking and alcohol use will be collected in both cohorts. RA duration and DAS28 will be recorded in the RA cohort only. The protocol does not specify which DAS28 variant (ESR/CRP) will be used; this should be defined consistently across sites.

Overactive Bladder Symptom Score (OABSS)

Four self-report items assessing daytime frequency, nocturia, urgency and urgency urinary incontinence; total score 0–15, with higher values indicating more severe symptoms. The validated Turkish version will be administered. Any diagnostic threshold or case definition based on OABSS must be prespecified before analysis.

ICIQ-UI Short Form

Assessment of frequency of urinary leakage, amount of leakage and interference with everyday life. The three scored components yield a total score of 0–21; higher scores indicate greater severity and impact. The circumstances-of-leakage item provides descriptive clinical information. The validated Turkish version will be used.

Incontinence Impact Questionnaire–7 (IIQ-7)

Seven items covering the effect of incontinence on physical activities, travel, social functioning and emotional health; each item has response categories scored 0–3. A

prespecified total scoring approach, including any conversion to a standardized scale, is required for consistent reporting across centers.

8. Outcome measures: proposed registry wording

The ethics application describes multiple symptom measures but does not select one uniquely defined primary endpoint. For registration, the following are proposed operationalizations and must be approved by the investigators before final submission.

Proposed primary outcomes

1. Prevalence of urinary incontinence in each cohort, assessed with the ICIQ-UI SF at the single study visit; expressed as the percentage reporting urinary leakage under a prespecified scoring rule (to be finalized). Time frame: baseline/single study visit (approximately 15–20 minutes).

2. OAB symptom severity, measured as the total OABSS score (0–15) at the single study visit; higher scores indicate greater symptom severity. Time frame: baseline/single study visit.

Proposed secondary outcomes

ICIQ-UI SF total score (0–21); OABSS item-specific frequency/severity of daytime frequency, nocturia, urgency and urgency UI; IIQ-7 total score for urinary symptom–related quality of life; prevalence of OAB using a prespecified symptom-based or OABSS definition; associations between DAS28 and symptom scores within the RA cohort. All assessed at the single study visit. Any outcome labeled prevalence requires a documented numerator/denominator definition.

9. Sample size justification

The source protocol assumes a prevalence of lower urinary tract symptoms of 60% in the RA cohort and 40% in controls, with two-sided alpha 0.05 and 80% power. Using G*Power 3.1, the application reports a minimum of approximately 95 participants per group to detect the anticipated 20-percentage-point difference. The target was expanded to 450 participants per cohort (900 total) to support subgroup analyses, account for missing data, and assess between-center heterogeneity. The exact G*Power test and settings should be retained or verified by the study statistician before submission.

10. Statistical analysis plan

Analyses will be performed in SPSS. Continuous variables will be described using mean and standard deviation or median and interquartile range, as appropriate; categorical variables will be summarized by frequency and percentage. Between-cohort comparisons will use an independent-samples t test or Mann–Whitney U test for continuous outcomes and chi-square tests for categorical outcomes, subject to assumptions and cell sizes. Pearson or Spearman correlation will assess associations among relevant numerical

variables. Multivariable logistic regression will explore factors associated with predefined binary urinary symptom outcomes, including cohort membership and measured covariates; within-RA analyses may include disease duration and DAS28. Two-sided $p<0.05$ will denote statistical significance, as in the source application. Analyses should additionally report effect estimates with 95% confidence intervals.

Before locking the statistical analysis plan, investigators should specify the primary binary case definitions, covariate selection, center effects, matching method (if any), missing-data rules, handling of multiplicity and whether a sensitivity analysis is appropriate. These aspects are not sufficiently operationalized in the submitted ethics application and are not represented here as already approved methods.

11. Ethics, confidentiality and participant rights

Participation is voluntary and requires written informed consent. Participants may decline individual questions or withdraw at any time without affecting clinical care. No trial-specific treatment, biological samples or invasive procedures are planned. Questionnaires and study records will be held securely, with restricted access and coded records, in accordance with applicable Turkish personal data protection requirements (KVKK). The source application specifies retention for at least five years. It contains differing descriptions of recording participant initials versus collecting no directly identifying information; the final site data-management procedure should resolve this discrepancy. Ethics review application identifiers are available, but approval date, decision and committee approval number have not been established from the supplied document.

12. Data quality and management

Trained site staff will use standardized questionnaire instructions and consistent coding conventions. The coordinating investigator will oversee completeness, appropriate storage and data quality. A site-specific participant code should be used for analysis datasets. Any identifier link should be separately stored, access restricted and retained only where permitted by consent and local requirements. Any changes to approved study procedures will be submitted to the relevant ethics committee as required.

13. Study timeline and discontinuation

The planned study period is 180 days. Participants undergo a single cross-sectional assessment and no longitudinal follow-up. Participants who withdraw will not require study-specific follow-up; handling of previously gathered data will follow the consent form and applicable requirements. Actual first-enrollment, primary completion and study completion dates must be supplied from study records rather than inferred from the ethics application date.

14. ClinicalTrials.gov registration field checklist

Study Type	Observational
Official Title	Prevalence of Overactive Bladder Symptoms and Urinary Incontinence and Their Impact on Quality of Life in Women With Rheumatoid Arthritis: A Multicenter Cross-Sectional Study With Healthy Controls
Brief Title	Urinary Symptoms and Quality of Life in Women With Rheumatoid Arthritis
Observational Model	Cohort (two predefined groups evaluated cross-sectionally); verify registry field choice
Time Perspective	Cross-Sectional
Enrollment (Estimated)	900
Number of Groups/Cohorts	2
Group 1	Women with rheumatoid arthritis
Group 2	Healthy female controls
Interventions	None
Conditions	Rheumatoid Arthritis; Overactive Bladder; Urinary Incontinence
Sex	Female
Age	20 years to 60 years
Healthy Volunteers Accepted	Yes
Sampling Method	Non-probability sample (confirmation required)
Overall Status	[CONFIRM from actual recruitment status]
Study Start / Primary Completion / Completion	[ENTER confirmed actual or estimated dates]
Study ID	[ASSIGN sponsor protocol identifier]
Sponsor and Collaborators	[CONFIRM lead sponsor and participating sites]
Ethics Committee	Ege University Medical Research Ethics Committee; approval status/date/number [VERIFY]
Responsible Party and contact	[CONFIRM nominated registry account holder and public contact]
IPD Sharing Statement	[DECIDE and document; not specified in source]

15. Brief summary for registry

This multicenter, observational, cross-sectional study aims to evaluate the prevalence and severity of overactive bladder symptoms and urinary incontinence among women with rheumatoid arthritis compared with healthy female controls and to examine their impact on quality of life. Approximately 900 women aged 20–60 years (450 with rheumatoid arthritis and 450 controls) will be recruited from participating rheumatology and rehabilitation outpatient clinics in Türkiye. Participants will complete validated Turkish

versions of the Overactive Bladder Symptom Score, the International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form and the Incontinence Impact Questionnaire–7 during a single study visit. Sociodemographic characteristics will be recorded in both cohorts; disease duration and disease activity assessed using DAS28 will additionally be recorded in the rheumatoid arthritis cohort. No investigational treatment, allocation, invasive procedure or follow-up intervention is planned. Analyses will compare urinary symptom burden and symptom-related quality of life between cohorts and explore associated demographic and disease-related factors.

16. Items requiring confirmation before registration

- Actual study recruitment status and calendar dates (start, primary completion, completion).
- Final ethics committee approval and approval date/number (application number alone is insufficient).
- Registry sponsor, responsible party, centralized contact details and final recruiting sites.
- Exact primary outcome definitions, especially UI and OAB prevalence thresholds, and whether co-primary endpoints are intended.
- Exact matching procedure, recruitment/sampling method and whether center clustering will be modeled.
- DAS28 variant and IIQ-7 score transformation/scoring conventions.
- Public data-sharing declaration and finalized privacy/identifiers procedure.
- Whether retrospective registration is required if recruitment has already begun.

17. Selected references from submitted application

1. Lee KL et al. Lower urinary tract symptoms in female patients with rheumatoid arthritis. Scand J Rheumatol. 2006;35(2):96–101.

2. Aras H et al. Frequency of Lower Urinary Tract Symptoms and Effects on Quality of Life in Women with Rheumatoid Arthritis. Turk J Phys Med Rehab. 2015;61:99–105.

3. Abushamma F et al. Lower Urinary Tract Symptoms Among Females with Rheumatoid Arthritis: A Prospective Cross-Sectional Study. Int J Gen Med. 2021;14:8427–8435.

4. Prevoo MLL et al. Validation of a new disease activity score for rheumatoid arthritis based on a reduced joint count. Arthritis Rheum. 1995;38(1):44–48.

5. Cam C et al. Validation of the short forms of the incontinence impact questionnaire (IIQ-7) and the urogenital distress inventory (UDI-6) in a Turkish population. Neurourol Urodyn. 2007;26(1):129–133.

6. Culha MG et al. Turkish validation of the overactive bladder symptom score (OABSS) and evaluation of mirabegron treatment response. Int Urogynecol J. 2019;30(12):2121–2126.