

Understanding how intestinal immune cells contribute to the development and activity of IgA nephropathy

Submission date 22/03/2026	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/04/2026	Overall study status Ongoing	<input type="checkbox"/> Protocol
Last Edited 11/05/2026	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

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Additional identifiers

Study information

Scientific Title

The role of intestinal mucosal B cells in the pathogenesis and activity of IgA nephropathy

Study objectives

The aim of this study is to investigate the role of intestinal mucosal B cells in the pathogenesis and activity of IgA nephropathy by identifying the origin, phenotype, and molecular characteristics of GdIgA1-producing B cells in intestinal lymphoid tissue and peripheral blood.

Ethics approval required

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Ethics approval(s)

approved 20/06/2025, Central Medical Ethics Committee of Latvia (72 k-1 Brīvības Street, Riga, LV-1002, Latvia; +371 (0)67876182; pasts@vm.gov.lv), ref: 01-29.1.2/3696

Primary study design

Observational

Secondary study design

Cohort study

Study type(s)

Health condition(s) or problem(s) studied

IgA nephropathy

Interventions

This is an observational quantitative cross-sectional study including patients with biopsy-proven IgA nephropathy and controls from the general population. Blood, urine, and intestinal biopsy samples (Peyer's patches) will be collected during colonoscopy. Peripheral blood mononuclear cells and intestinal immune cells will be isolated and analyzed using flow cytometry, ELISA, and RNA sequencing (bulk RNA-seq and single-cell RNA sequencing) to characterize B cell subpopulations and GdIgA1 production. In vitro B cell stimulation and co-culture models will be used to evaluate mechanisms of GdIgA1 production and B cell activation. Immunofluorescence microscopy will be used to analyze intestinal lymphoid tissue. Clinical and laboratory data will be collected and compared between study groups. Statistical analysis will be performed to identify differences between groups and associations between immunological markers and disease activity.

Intervention Type

Other

Primary outcome(s)

1. Frequency and molecular characterization of GdIgA1-producing B cells measured using flow cytometry, ELISA measurement of GdIgA1, and RNA sequencing (bulk RNA-seq and single-cell RNA sequencing) of B cells isolated from peripheral blood and intestinal Peyer's patches at the time of sample collection during study visit (single timepoint)

Key secondary outcome(s)

Completion date

31/12/2027

Eligibility

Key inclusion criteria

Cases – IgAN group:

1. Adults (≥ 18 years)
2. Biopsy-proven IgA nephropathy
3. eGFR ≥ 45 ml/min/1.73 m²
4. Proteinuria < 1 g/day
5. Indication for colonoscopy (anemia, change in bowel habits, abdominal pain, positive fecal occult blood test)

Controls:

1. Adults (≥ 18 years)
2. Individuals from general population undergoing screening colonoscopy
3. Positive fecal occult blood test
4. No pathological findings in colonoscopy (no polyps, tumors, inflammation)

Healthy volunteers allowed

Yes

Age group

Mixed

Lower age limit

18 years

Upper age limit

99 years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Age <18 years
2. Pregnancy or breastfeeding
3. Secondary IgA nephropathy
4. IgA vasculitis
5. Liver disease
6. Alcoholism
7. Type 1 or type 2 diabetes mellitus
8. Chronic inflammatory diseases
9. Malignancy
10. Acute myocardial infarction or stroke within the last 6 months
11. Active gastrointestinal bleeding

For control group: polyps, tumors, or inflammatory changes detected during colonoscopy

Date of first enrolment

01/04/2026

Date of final enrolment

01/05/2027

Locations

Countries of recruitment

Latvia

Study participating centre

Pauls Stradiņš Clinical University Hospital

Department of Nephrology

Riga

Latvia

LV-1002

Study participating centre

Rīga Stradiņš University

-

Riga

Latvia

LV-1007

Sponsor information

Organisation

Fundamental and Applied Research Projects in Latvia

Funder(s)

Funder type

Funder Name

Fundamental and Applied Research Projects in Latvia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available