Participant Information Sheet

Retrospective Data Use Notice

Public study title	**Which clinical features are linked with severe presentation in people tested for anti-GBM antibodies?**
Scientific title	Clinical characteristics and CRI-defined high-risk presentation among adults evaluated for anti-glomerular basement membrane antibodies: a retrospective cross-sectional analytical study at Baoding No.1 Central Hospital
Version/date	Version 1.0 - 28 September 2026
Study institution	Baoding No.1 Central Hospital
Principal contact	Wenjie Song - 18132745298@163.com
Ethics reference	IRB-A27N5-2026

Why is this study being done?

Anti-GBM antibodies can be associated with serious kidney and lung disease, but not every patient has the same level of illness at first presentation. The study examines existing clinical records to describe these different presentations and to evaluate a structured CRI classification of high-risk and lower-risk presentation among anti-GBM-positive patients.

Why might my record be included?

Your record may be included if you were aged 18 years or older, underwent anti-GBM antibody testing during routine clinical care between 1 January 2021 and 31 December 2025, and the record contains the core information needed for the study. Only the first eligible index presentation is used for each patient.

Do I need to do anything?

No. This is a retrospective study using information that already exists in hospital records. There is no additional appointment, questionnaire, blood test, scan, biopsy, medication, or other intervention for this research, and patients are not contacted for study procedures.

What information is used?

Relevant information may include age and sex; kidney-function and other blood tests; urine findings; anti-GBM and ANCA antibody results; symptoms such as breathlessness or coughing blood; chest imaging; dialysis status; and renal biopsy findings where available. The information is limited to data needed to answer the research questions.

How is my privacy protected?

Research data are de-identified before analysis and are handled under Baoding No.1 Central Hospital research-governance procedures. Access is limited to authorized members of the research team. Findings

are reported in grouped form and publications or registry records will not identify individual patients. Any sharing of de-identified study data is subject to institutional approval and applicable privacy requirements.

What are the possible benefits and risks?

There is no direct benefit to an individual patient because the study does not change clinical care. The research may improve understanding of how anti-GBM-positive patients differ in presentation severity and may support future prospective research. The principal risk is an unintended loss of confidentiality; de-identification, controlled access, and aggregate reporting are used to reduce that risk.

Was consent required?

The Medical Ethics Committee of Baoding First Central Hospital approved the study and waived the requirement for written informed consent because the research uses existing de-identified clinical records, involves no direct participant contact, and adds no study procedures. Ethics approval was granted on 15 January 2026 under reference IRB-A27N5-2026.

What will happen to the results?

The results may be submitted to a clinical study registry, presented at scientific meetings, and published in peer-reviewed journals. Results are reported at group level. De-identified supporting data may be considered for sharing on reasonable request only where institutional and privacy requirements permit.

Who is funding the study?

Medical Science Research Project of Hebei Province (Project No. 20251434).

Conflict of interest

None.

Who can I contact?

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For questions about research ethics or the use of clinical records: Medical Ethics Committee of Baoding First Central Hospital, No. 320 Changcheng North Street, Lianchi District, Baoding, Hebei 071000, China; telephone +86 312 5976679; reference IRB-A27N5-2026.