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Real-world experience of patients with IgA nephropathy treated with sparsentan through an Early Access Program in the UK

Submission date
16/09/2026

Recruitment status
Recruiting

Registration date
16/09/2026

Overall study status
Ongoing

Last Edited
16/09/2026

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Immunoglobulin A nephropathy (IgAN) is a disease in which an antibody called immunoglobulin A builds up in the kidneys, causing inflammation and damage. Over time, some patients develop progressive loss of kidney function and may eventually require dialysis or a kidney transplant. One of the main signs of disease activity is excess protein in the urine (proteinuria). Reducing proteinuria is linked to better long-term kidney outcomes.
Sparsentan is a medicine approved for the treatment of adults with primary IgA nephropathy who are at risk of disease progression. Before routine availability within the NHS, eligible patients could receive sparsentan through an Early Access Program. While clinical trials have shown that sparsentan can reduce proteinuria, it is important to understand how the treatment performs in routine clinical practice.
The aim of this study is to evaluate the real-world effectiveness of sparsentan in patients with IgA nephropathy treated through the Early Access Program. The study will also examine kidney function, treatment duration, blood pressure and other laboratory measurements recorded during routine care.

Who can participate?
Patients aged 18 years or older with IgA nephropathy who received sparsentan through the Early Access Program and who have not opted out of participation in this research.

What does the study involve?
This is an observational study using information already recorded in patients' medical records. No additional clinic visits, tests, procedures or treatments are required as part of the research. Eligible patients are informed about the study and given the opportunity to opt out. For patients who do not opt out, information is collected retrospectively from routine medical records. The information collected includes patient characteristics, medical history, laboratory results, kidney function measurements, blood pressure, details of sparsentan treatment and reasons for treatment discontinuation where applicable.

Patients are followed from the start of sparsentan treatment until treatment discontinuation or the end of available follow-up. Data are analysed after collection and used to understand treatment outcomes in routine clinical practice.

What are the possible benefits and risks of participating?
Participants are unlikely to receive any direct benefit because the study does not alter treatment or clinical care. However, the information collected may help improve understanding of how sparsentan performs in routine practice and may support the care of future patients with IgA nephropathy.
The study is considered low risk because it uses information already collected during routine care. The main risk relates to confidentiality. To minimise this risk, study data are pseudonymised before being shared with the research team and only the minimum information required for the study is collected.

Where is the study run from?
The study is led by University Hospitals of Leicester NHS Trust (UK) and is coordinated by Bionical Emas. Participating NHS hospitals across the UK contribute data.

When is the study starting and how long is it expected to run for?
August 2026 to March 2027

Who is funding the study?
Vifor (International) AG (CSL Vifor) (Switzerland)

Who is the main contact?
Dr Chee Kay Cheung, cheekay.cheung@nhs.net

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Principal investigator, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
348374

Central Portfolio Management System (CPMS)
64710

Sponsor protocol number
SPAR-RWE-EAP-UK

Study information

Scientific Title
A multicentre, retrospective, observational real-world data study evaluating the effectiveness, treatment characteristics and clinical outcomes of sparsentan in patients with primary IgA nephropathy treated through an Early Access Program

Study objectives
1. To evaluate the effectiveness of sparsentan in a real-world clinical setting in patients with primary IgA nephropathy treated through an Early Access Program
2. To examine changes in kidney function and clinical outcomes from baseline over time
3. To describe sparsentan treatment characteristics, including dose and treatment duration
4. To describe changes in relevant laboratory parameters from baseline over time
5. To describe changes in blood pressure from baseline over time

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/06/2025, London - Queen Square Research Ethics Committee (Floor 2 2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8000; queensquare.rec@hra.nhs.uk), ref: 25/PR/0415

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Immunoglobulin A (IgA) nephropathy

Interventions
Participants are not assigned to any treatment or intervention as part of this study. Clinical and laboratory data are collected from routine medical records for patients with Immunoglobulin A (IgA) nephropathy. Information collected may include patient demographics, medical history, disease characteristics, laboratory assessments, treatment history, concomitant medications, and clinical outcomes. Data are entered into an electronic data capture system by authorised site personnel. No additional tests, procedures, or study-specific visits are required, and all treatment decisions remain at the discretion of the treating physician as part of routine clinical practice.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sparsentan

Primary outcome(s)
1. Proteinuria remission measured using the proportion of patients achieving complete proteinuria remission (<0.3 g/day proteinuria) during follow-up, measured at sparsentan initiation until treatment discontinuation or end of available follow-up

2. Partial proteinuria remission measured using the proportion of patients achieving partial proteinuria remission (<1 g/day proteinuria or urine protein-to-creatinine ratio <0.75 g/g) during follow-up, measured at sparsentan initiation until treatment discontinuation or end of available follow-up

Key secondary outcome(s)
1. Proteinuria measured using urine protein excretion and/or urine protein-to-creatinine ratio obtained from routine clinical laboratory assessments and medical records, measured at baseline, 3 to 4 weeks after sparsentan initiation, and approximately every 3 to 6 months until treatment discontinuation or end of data collection

2. Albuminuria measured using urine albumin measurements obtained from routine clinical laboratory assessments and medical records, measured at baseline, 3 to 4 weeks after sparsentan initiation, and approximately every 3 to 6 months until treatment discontinuation or end of data collection

3. Estimated glomerular filtration rate (eGFR) measured using routine clinical laboratory assessments and medical records at baseline, 3 to 4 weeks after sparsentan initiation, and approximately every 3 to 6 months until treatment discontinuation or end of data collection

4. Annual rate of change in eGFR measured using serial routine clinical laboratory assessments. at sparsentan initiation until treatment discontinuation or end of data collection

5. Kidney disease progression measured using the proportion of patients experiencing confirmed 40% reduction in eGFR, kidney failure (eGFR <15 ml/min/1.73m² or initiation of renal replacement therapy), or renal death, measured at sparsentan initiation until treatment discontinuation or end of data collection

6. Sparsentan treatment characteristics measured using the average daily sparsentan dose prescribed and time from treatment initiation to treatment discontinuation, recorded from medical records at treatment initiation until treatment discontinuation or end of data collection

7. Laboratory parameters: haemoglobin, potassium, serum creatinine, serum cystatin C, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) measured using routine clinical laboratory assessments at baseline, 3 to 4 weeks after sparsentan initiation, and approximately every 3 to 6 months until treatment discontinuation or end of data collection

8. Blood pressure: seated systolic and diastolic blood pressure measured using routine clinical visits at baseline, 3 to 4 weeks after sparsentan initiation, and approximately every 3 to 6 months until treatment discontinuation or end of data collection

Completion date
31/03/2027

Eligibility

Key inclusion criteria
1. Adults aged 18 years or older
2. Primary IgA nephropathy (IgAN)
3. Received sparsentan through the Early Access Program (EAP)
4. Have not opted out of participation

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patients with an existing NHS National Data Opt-Out
2. Patients who choose to opt out of participation after receiving the study opt-out letter
3. Patients not treated with sparsentan through the Early Access Program for IgA nephropathy

Date of first enrolment
24/08/2026

Date of final enrolment
28/02/2027

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road
London
England
SE1 7EH

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
England
E1 2ES

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
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B15 2GW

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
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Scotland
EH1 3EG

Study participating centre
Northern Care Alliance NHS Foundation Trust
Salford Royal
Stott Lane
Salford
England
M6 8HD

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Royal Preston Hospital
Sharoe Green Lane
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PR2 9HT

Sponsor information

Organisation
Vifor International AG

Funder(s)

Funder type

Funder Name
Vifor International AG

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available