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Stabilization of kidney function in patients diagnosed with primary immunoglobulin A nephropathy by treatment with a locally-acting corticosteroid formulation – budesonide

Submission date
12/02/2020

Recruitment status
No longer recruiting

Registration date
14/02/2020

Overall study status
Completed

Last Edited
20/11/2023

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
IgA nephropathy, also known as Berger's disease, is a kidney disease that occurs when an antibody called immunoglobulin A (IgA) builds up in the kidneys. This results in local inflammation that, over time, can hamper the kidneys' ability to filter waste from the blood. Treatment of IgA nephropathy (IgAN) is a matter of debate and while corticosteroids remain the most effective in preventing disease progression, their use is limited by important side effects. This study aims to evaluate the efficacy of budesonide (Budenofalk®) in the treatment of patients with IgA Nephropathy.

Who can participate?
Patients aged 18 years or above with IgA nephropathy and persistent proteinuria.

What does the study involve?
Patients receive treatment with Budesonide for up to 36 months.

What are the possible benefits and risks of participating?
The benefit include the possibility of being treated and followed in a tertiary clinic, with high experience in managing the patients with IgA Nephropathy. This study doesn’t carry any risk associated with the participation, other than that related to the risk associated with diagnostic procedures (percutaneous kidney biopsy) and the possibility of minimal steroid-related side-effects.

Where is the study run from?
Fundeni Clinical Institute, Department of Nephrology (Romania)

When is the study starting and how long is it expected to run for?
March 2020 to December 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1975

Study information

Scientific Title
An open-label study evaluating the efficacy and safety of budesonide in the treatment of patients with immunoglobulin A nephropathy

Acronym
BUDIGAN

Study objectives
Gut-associated lymphoid tissue production (GALT) of the immunoglobulin A1 with a characteristic galactosylation defect in the hinge region of the molecule is the first pathogenic event in the course of IgA nephropathy. Targeting GALT dysregulation with a pH-modified formulation of budesonide with a maximum release in the distal ileum and proximal colon offers the premise of a safer approach than systemic corticosteroids for the treatment of IgA nephropathy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/12/2019, The Ethics Council of Fundeni Clinical Institute (Sos. Fundeni, Nr. 258, Sector 2, Bucharest, 022328, Romania; +40 212750500; etica@icfundeni.ro), ref: 1975

Study design
Prospective interventional open-label single-center non-randomised study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Patients receive treatment with budesonide at a dose of 9 mg/day for the first 12 months, subsequently tapered to 3 mg/day for another 12-24 months.

Intervention Type

Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Budesonide (Budenofalk®)

Primary outcome(s)
At baseline and 36 months:
1. Estimated glomerular filtration rate
2. Extent of proteinuria and hematuria
3. MESTC score assessed by kidney biopsy

Key secondary outcome(s))
Incidence of budesonide-related adverse events over the 36 months

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Patients with a histological diagnosis of IgA nephropathy
3. Patients with primary IgA nephropathy
4. Patients with persistent proteinuria over 1g/day despite adequate renin-angiotensin-aldosterone system (RAAS) blockade or patients with proteinuria between 0.5 and 1 g/day after RAAS blockade if they had additional risk factors for progression (estimated glomerular filtration rate below 60 ml/min/1.73m², presence of proliferative lesions on kidney biopsy)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
32

Key exclusion criteria

1. IgAN associated with other disorders (viral infections, autoimmune disorders, malignancy)
2. Estimated glomerular filtration rate below 20 ml/min/1.73m²
4. Nephrotic syndrome or a rapidly progressive clinical course
5. Proteinuria below 0.5 g/day after adequate RAAS blockade.
6. Severe histological lesions of activity or chronicity (endocapillary hypercellularity in over 50% of examined glomeruli, crescents in over 30% of examined glomeruli, presence of fibrinoid necrosis, global glomerulosclerosis in over 50% of examined glomeruli)
7. Diabetes mellitus or active infections
8. Received prior immunosuppression

Date of first enrolment
01/03/2020

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Romania

Study participating centre
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Sponsor information

Organisation
Institutul Clinic Fundeni

ROR
https://ror.org/05w6fx554

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/11/2023	20/11/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes