

Facts:

- IgA nephropathy, also known as Berger's disease, is a common condition that damages the kidneys.
- About 10-30% of people with IgA nephropathy develop progressive renal failure, leading to end-stage kidney disease requiring dialysis or kidney transplantation.
- Effective and proven therapy options are limited and there is a lack of clinical evidence regarding corticosteroid use in IgA nephropathy.

Project cycle:

The study was initiated in 2012. It is an event-based study and will continue until 161 events are reached.

Partners:

The George Institute for Global Health Peking University First Hospital Sunnybrook Hospital Health Science Centre

Supporters:

The George Institute for Global Health National Health Medical and Research Council (NHMRC), Australia Peking University Clinical Research Institute Canadian Institutes of Health Research Pfizer

Background:

- Despite Immunoglobulin A Nephropathy (IgA nephropathy) being the most common cause of end-stage kidney disease in young adults, few studies have examined regional differences around the world, and current treatment guidelines are based on trials without a uniform approach or adequate sample sizes - especially for individuals with a high risk of kidney progression.
- Corticosteroid use in IgA nephropathy has been widely used for decades, despite a significant gap in evidence for dosing and duration of this therapy. As a result, there is significant regional variability and clinical uncertainty regarding corticosteroid use in IgA nephropathy.

<u>Aims:</u>

- TESTING, an investigator-initiated randomised controlled trial (RCT), aims to close the evidence gap regarding corticosteroid use in individuals with IgA nephropathy.
- Upon completion, TESTING will be the largest RCT to provide the most up-todate robust evidence on the net benefit versus harm of corticosteroid use in IgA nephropathy.

Methods:

- With 70 participating sites, TESTING is a multicentre, double-blinded RCT involving investigators and participants from Australia, Canada, China, Hong Kong, India and Malaysia.
- In November 2017, the study was temporarily halted due to high levels of side effects among participants receiving corticosteroid. However, an interim analysis found clear signals that corticosteroid may prevent individuals with IgA nephropathy from developing renal failure. The study protocol was modified and recruitment recommenced.
- In November 2019, the trial successfully randomised its target of 503 participants, becoming the largest RCT in IgA nephropathy in the world to date.

Impact:

- TESTING aims to resolve persisting uncertainties regarding corticosteroid as a therapy for IgA nephropathy.
- Trial outcomes will provide the most robust evidence for clinicians on the use of corticosteroid (duration and dosing) and potential side effects.
- This evidence will help consumers make an informed choice on corticosteroid therapy and guide joint decision making.
- TESTING results will change international guidelines on the management of IgA nephropathy.

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