

“ Novoglan foreskin tissue expander has been clinically proven to treat Phimosis in selected men ”



PROFESSOR  
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*Independent Principal Investigator*

“ Novoglan foreskin tissue expander device is a safe & effective treatment for adult phimosis ”



PROFESSOR  
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*Independent Investigator*

**90%+**

- ✓ Treatment **efficacy**
- ✓ Patient **recommendation**

- ✓ Excellent **safety** profile
- ✓ Excellent **tolerability** profile



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## NOVOGLAN DEVICE FOR TREATMENT OF ADULT PHIMOSIS

### Novoglan-01 open-label clinical trial on safety, efficacy and tolerability

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#### BACKGROUND

At present, the only definitive treatment for adult phimosis is circumcision, which is a surgical removal of the prepuce. Novoglan is a novel device that could offer patients with phimosis an alternative to surgery. It is based on application of custom-moulded balloons for gradual skin remodeling and prepuce dilatation. This open-label clinical trial aimed to investigate the safety, efficacy and tolerability of the Novoglan treatment.

#### METHODS

A prospective trial was conducted on 20 patients with adult phimosis recruited at Macquarie University Hospital and Princess Alexandra Hospital. After eligibility screening and enrolment, patients were provided with the Novoglan product and training. The treatment involved twice daily 10-minute applications for a duration of 4–8 weeks with patient's degree of phimosis assessed before and at 6–8 weeks after the initiation of the treatment. Participants were also asked to complete questionnaires aimed to assess the safety and tolerability of the Novoglan treatment.

#### CONCLUSIONS

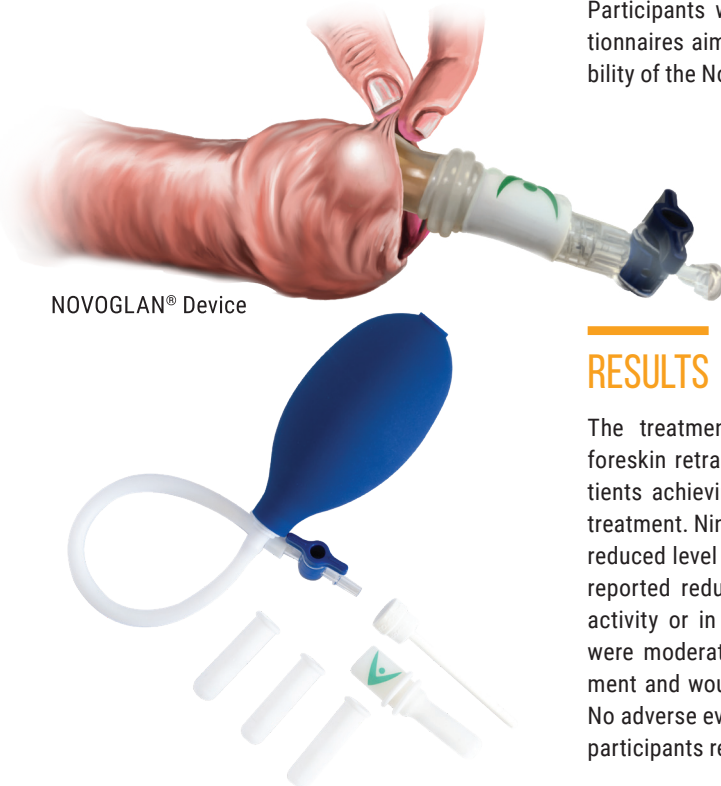
The Novoglan-01 trial demonstrated high safety, efficacy and tolerability of the Novoglan treatment for adult phimosis and its high potential as a conservative alternative to circumcision or steroid cream treatment.

#### KEYWORDS

Phimosis; adult male phimosis; circumcision; conservative treatment of phimosis

#### TRIAL REGISTRATION

The Novoglan-01 study has been registered with the Australia and New Zealand Clinical Trial Registry under the reference ACTRN 1262 10009 24853, dated 15 July 2021.



#### RESULTS

The treatment was successful with improved foreskin retraction in 90% of patients and all patients achieving full foreskin retraction after the treatment. Ninety-five percent of patients reported reduced level of anxiety, and over 60% of patients reported reduced pain/discomfort during sexual activity or in general. Similarly, 95% of patients were moderately-to-very satisfied with the treatment and would recommend Novoglan to others. No adverse events were observed and only 15% of participants reported minor side effects.

#### KEY FINDINGS

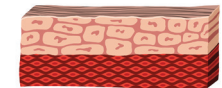
- The Novoglan treatment is safe, effective and highly tolerable alternative to circumcision in adults with phimosis with all patients achieving foreskin retraction after the treatment.

#### What is known and what is new?

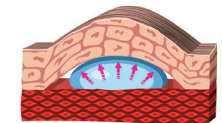
- Circumcision remains the standard of care for treatment of adult phimosis, however many patients would prefer non-surgical approach.
- Novoglan-01 clinical trial has shown that non-surgical Novoglan treatment could improve foreskin retraction in adults with phimosis without significant side effects or discomfort.

#### What is the implication, and what should change now?

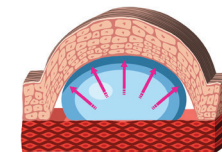
- The findings of the Novoglan-01 clinical trial demonstrate high potential of Novoglan as a conservative first line treatment in adults with phimosis.



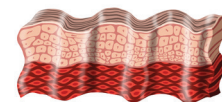
1. PRE TREATMENT



2. EARLY TREATMENT



3. PROGRESSIVE TREATMENT



4. POST TREATMENT

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