UAA2022
19th UROLOGICAL ASSOCIATION OF ASIA CONGRESS
SYDNEY | OCTOBER 5-8

Interim review of the Novoglan-01 foreskin tissue expander clinical study in adult males

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INTRODUCTION

The main therapeutic options for pathologic adult phimosis consist of circumcision, manual preputial stretching with steroid creams and foreskin tissue expanders such as the Novoglan product. Circumcision and preputial stretching with cortico-steroid creams can frequently be successful but are far from simple and can lead to severe complications that the Novoglan product is designed to prevent. The Novoglan-01 study is an investigator-initiated study that aims to demonstrate the safety, efficacy and tolerability of the Novoglan treatment.

AIM

The Novoglan-01 clinical trial primary objective is to confirm the efficacy of the Novoglan product as measured by the improvement in foreskin retraction against a standardised scale by the end of a typical 6 to 8 weeks treatment. The Novoglan-01 trial secondary objective is to confirm the safety and satisfaction with treatment as assessed by quality of life improvement and treatment tolerability questionnaires. .

METHOD

We analysed the case report files of the first 20 cases having completed the Novoglan-01 clinical trial treatment protocol. The statistical methods used in analyzing the data involve both ordinal and scalar outcome variables as well as descriptive participant variables.

RESULTS

Participant journey

Week 0 – Enrolment + informed consent

Week 1 – Study Visit 1 + Novoglan product training + Phimosis measurement + Quality of life (QOL) questionnaire

Week 2 – Study Visit 2 – Monitoring

Week 4 – Study Visit 3 – Monitoring

Week 6 – Final Study Visit + Phimosis measurement + QOL questionnaire + tolerability questionnaire

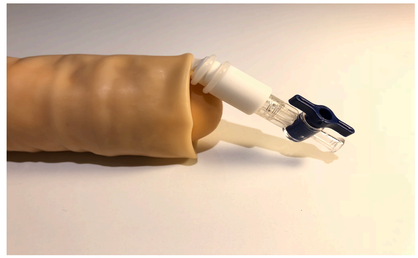
Phimosis measurement

Carried out by investigator – Assessment of degree of phimosis based on a 6 steps scale inspired by Kikiros et al. [1], ranging from:

1 = absolutely no foreskin retraction, to

6 = full and free foreskin retraction

Novoglan product



Treatment efficacy

The treatment efficacy observed by the end of treatment (Final Visit) was as follows.

- **All participants could fully retract their foreskin** (Phimosis measurement 5 or 6)
- **Participants with severe or partial phimosis** (Phimosis measurement 1, 2, 3 or 4) **observed the most improvement with full foreskin retraction** (Phimosis measurement 5 or 6)

Treatment safety

The Novoglan treatment shows a strong safety profile.

- **85% of participants did not report any side effects at all.** Only minor side effects were reported by 15% of participants.
- **No adverse event** was reported.

Treatment tolerability

- Participant questionnaires show that **95% of participants reported satisfaction** with the Novoglan treatment .

Other outcomes

Other study observed outcomes were as follows.

- **95% of study participants would recommend the Novoglan treatment to others.**
- **95% of study participants confirmed progressing well with the Novoglan treatment** during the study.
- **95% of participants observed reduced anxiety** following the Novoglan treatment.

The Novoglan-01 clinical trial is a multicenter (2 sites), observational study that has been approved by the Human Research Ethics Committee of Macquarie University and by the Queensland Metro South Health Human Research Ethics Committee. The Novoglan-01 clinical study is registered with the Australia and New Zealand Clinical Trial Register under the reference ACTRN12621000924853.

CONCLUSIONS

This interim review of the Novoglan-01 study confirms that the Novoglan foreskin tissue expander is safe, effective and well tolerated as a conservative treatment for adult phimosis.

REFERENCES

[1] **Kikiros D.S. et al**. The response of phimosis to local steroid application. *Pediatric Surgery International,* 1993 **8**:329-332

ACKNOWLEDGEMENTS

The authors wish to acknowledge Prof Gillatt's assistant, Mrs Maizie Barakat, who helped compile data for the study biostatistical analysis.

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