

Title: Clinical trial and post-marketing data on the use of Novoglan for conservative treatment of adult phimosis

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Purpose:

Novoglan is a medical device designed for adults with phimosis who wish to avoid circumcision. We conducted a post-marketing study and a clinical trial focusing on the safety, efficacy, and usability of the Novoglan treatment as well as its impact on mental wellbeing. To assess the reliability of the data collected from the post-marketing study and real-world applicability of the clinical trial data, we compared the findings from both studies.

Methods:

For the post-marketing study, questionnaires were emailed to the Novoglan users. Complete responses from 461 patients were de-identified and included in the analysis. The Novoglan-01 clinical trial recruited 20 participants, who were similarly asked to completed questionnaires and were assessed by a urologist before and after the treatment to assess the treatment results.

Results:

The treatment efficacy was similarly high in both studies with 93.5% of the Novoglan users deeming their treatment effective in the post-marketing study and improvement in foreskin retraction observed by urologists in 90% of the trial participants. The Novoglan product was reported easy to use by 91.8% of the post-marketing study participants and by all clinical trial participants. Positive impact on mental wellbeing was reported by 85.3% of the users in the post-marketing study, while more detailed assessment conducted in the clinical trial revealed reduced anxiety level in 95% of participants. Similarly, while no significant side effects were reported in the post-marketing study, more detailed questionnaires used in the clinical trial revealed transient foreskin discomfort, pain, itching or discoloration in 5-15% of participants.

Conclusion(s):

Both Novoglan post-marketing study and clinical trial demonstrated very high level of safety, efficacy and usability of the treatment and its positive impact on mental wellbeing. The comparison of the findings revealed that while more data could be obtained from detailed questionnaires used in the clinical trial, the overall similarity of the findings supports the reliability of both studies.