

# Elastargene 3C helps to improve glycated haemoglobin in children and adolescents with type 1 diabetes using insulin pump therapy

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## Introduction

Whilst insulin pumps give patients with diabetes opportunities to take glycemia under control, there are a number of common problems which can occur from time to time. Among them, dermatological ones are quite common but those taken into account less. Pump bumps and white scars are the most common, and they may lead sometime to inconsistent insulin delivery.

## Objectives

A 6-month, double-blind, RCT to test the efficacy of 3C-Elastargene in children with type 1 diabetes using insulin pump, has been conducted. The aim of the study was to evaluate the cream efficacy in improving patients' skin, healing and making disappear the white scars usually left after infusion set removal. Secondary aim was to evaluate any effect on metabolic control

## Methods

The cream : 3C-Elastargene (Colipex®, Harmonium Pharma, Italy) is an emollient and soothing skin care body cream, specifically designed to improve lipoatrophy in patients with diabetes. Among the active ingredients contained in this cream there are: Oenothera biennis oil, caffeine, Aloe barbadensis leaves juice Hydrolyzed collagen and elastin, Thymus vulgaris extract Fucus vesiculosus extract, Malaleuca alternifolia essential oil, Arnica montana extract, Hamamelis virginiana extract, L-carnitine. ELASTin, ARnica and collaGENE stand for Elastargene, while Caffeine, Collagen and L-Carintine for the '3C'.

Forty children and adolescents using insulin pump therapy, were randomized into 2 arms:

- n=20 3C-Elastargene once a day on the skin of abdomen or other sites where infusion sets have been placed, administered before sleeping;
- n=20 placebo once a day on the skin of abdomen or other sites where infusion sets have been placed, administered before sleeping.

BMI, HbA1c, insulin requirement, were determined in each child before starting the study and after 6 months.

	3C-E (n=18)	Placebo (n=17)	P
Age (yrs)	15.2±4.8	15.1±5.7	0.941
T1D (yrs)	8.0±5.3	8.3±5.8	0.749
CSII (yrs)	4.1±3.0	4.7±3.0	0.852
HbA1c (%)	8.08±0.80	7.98±0.74	0.593
IR (U/kg/day)	0.89±0.34	0.88±0.27	0.786
BMI (kg/m <sup>2</sup> )	22.7±1.2	21.9±2.3	0.822

Table Clinical characteristics of the two groups.

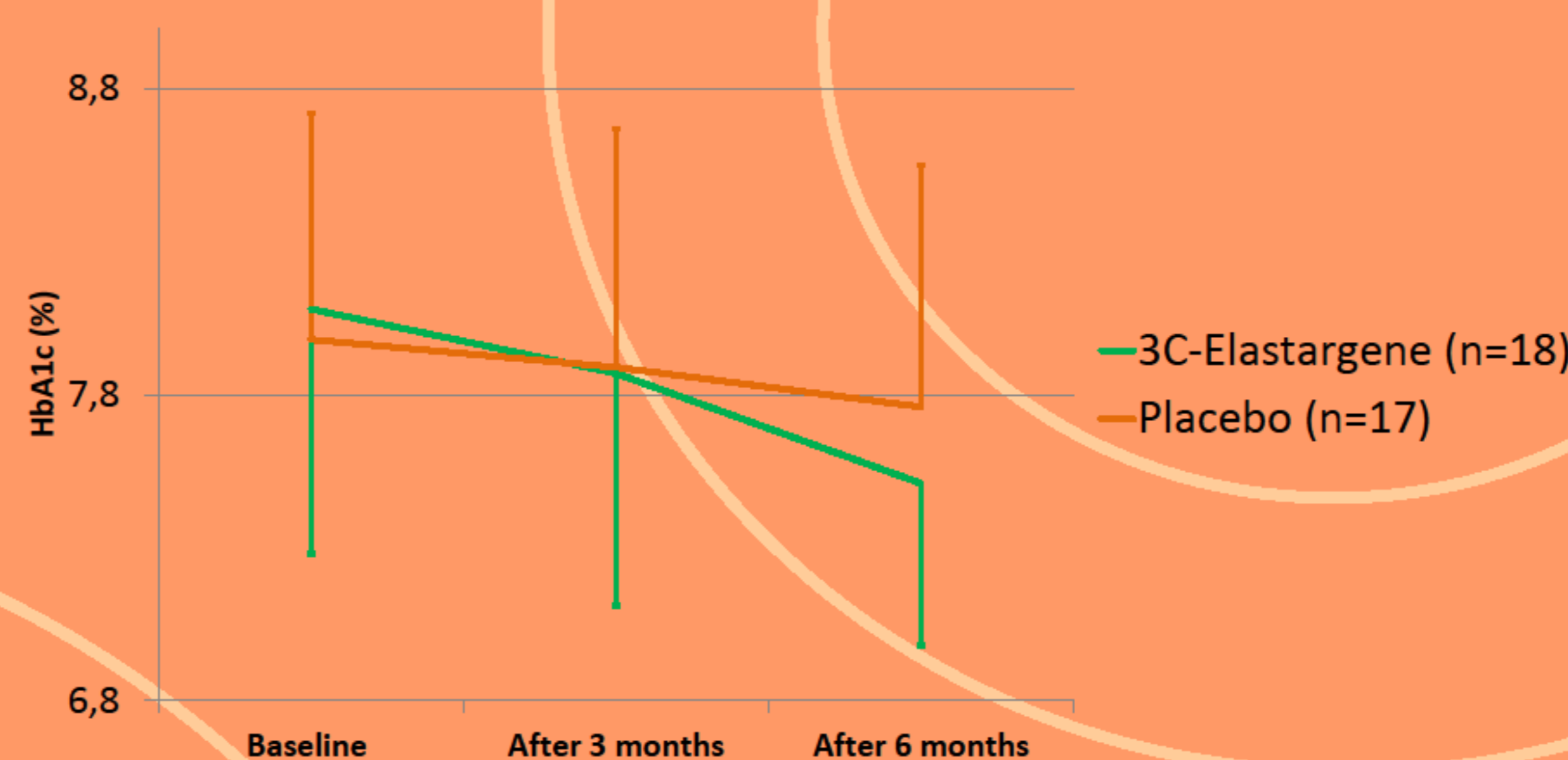


Figure 1 – HbA1c at baseline and after 6 months.



Figure 2A – Little white scars after infusion set discharge before 3C-E treatment.



Figure 2B – The same patient after 3C-E treatment; the little white scars have been disappeared

## Results

- At the end of the study, 5 patients dropped using the 3C-Elastargene cream (n=2) or placebo (n=3) and were excluded from the analysis. The characteristics of the patients studied are summarized in the Table; no significant statistical difference has been observed between groups regarding age, diabetes duration, time since using an insulin pump, HbA1c, insulin requirement and BMI.
- HbA1c significantly improved in patients using 3C-Elastargene (baseline 8.08±0.80%, after 6 months 7.51±0.53%, p=0.005, delta -0.53%), but not in placebo group (baseline 7.98±0.74%, after 6 months 7.76±0.79%, p=0.19, delta -0.22%) (Figure 1).
- No difference has been observed regarding BMI or insulin requirement before study vs after 6 months.
- In the 3C-Elastargene group, the scars completely disappeared in 8 patients (Figure 2) and improved in 10; in the placebo group the scars did not change in any of the patients.

## Conclusions

To our knowledge this is the first time that a direct effect of 3C-Elastargene have been shown to improve little white scars left on the skin after infusion set removal in children with type 1 diabetes using an insulin pump. Moreover, HbA1c significantly improved only in the 3C-Elastargene group, possibly because improved insulin absorption. These results need to be confirmed on larger groups, followed for a longer period. However, these findings seem very promising to improve quality of life of children and adolescents with type 1 diabetes, using insulin pump therapy, and to permit them to wear the pump without the fear of permanent scars on the skin.

## References:

- 1) Bell DS, Ackerson C, Cutter G, Clements RS Jr. Factors associated with discontinuation of continuous subcutaneous insulin infusion. Am J Med Sci 1988 Jan;295(1):23-8.
- 2) Binder E, Lange O, Edlinger M, Meraner D, Abt D, Moser C, Steichen E, Hofer SE. Frequency of dermatological side effects of continuous subcutaneous insulin infusion in children and adolescents with type 1 diabetes. Exp Clin Endocrinol Diabetes. 2015 Apr;123(4):260-4. doi: 10.1055/s-0034-1394381. Epub 2015 Jan 21.

