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Benhalima, K.[a b] , Beunen, K.[a] , Van Wilder, N.[c] , Ballaux, D.[d] , Vanhaverbeke, G.[e] , Taes, Y.[f] , Aers, X.-P.[g] , Nobels, F.[h] , Marlier, J.[i] , Lee, D.[j] , Cuypers, J.[k] , Preumont, V.[l] , Siegelaar, S.E.[m n] , Painter, R.C.[o p] , Laenen, A.[q] , Gillard, P.[a b] , Mathieu, C.[a b]

Comparing advanced hybrid closed loop therapy and standard insulin therapy in pregnant women with type 1 diabetes (CRISTAL): a parallel-group, open-label, randomised controlled trial

(2024) *The Lancet Diabetes and Endocrinology*, 12 (6), pp. 390-403. Cited 1 time.

DOI: 10.1016/S2213-8587(24)00089-5

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Abstract
Background: Advanced hybrid closed loop (AHCL) therapy can improve glycaemic control in pregnant women with type 1 diabetes. However, data are needed on the efficacy and safety of AHCL systems as these systems, such as the MiniMed 780G, are not currently approved for use in pregnant women. We aimed to investigate whether the MiniMed 780G can improve glycaemic control with less hypoglycaemia in pregnant women with type 1 diabetes. Methods: CRISTAL was a double-arm, parallel-group, open-label, randomised controlled trial conducted in secondary and tertiary care specialist endocrinology centres at 12 hospitals (11 in Belgium and one in the Netherlands). Pregnant women aged 18–45 years with type 1 diabetes were randomly assigned (1:1) to AHCL therapy (MiniMed 780G) or standard insulin therapy (standard of care) at a median of 10·1 (IQR 8·6–11·6) weeks of gestation. Randomisation was done centrally with minimisation dependent on baseline HbA1c, insulin administration method, and centre. Participants and study teams were not masked to group allocation. The primary outcome was proportion of time spent in the pregnancy-specific target glucose range (3·5–7·8 mmol/L), measured by continuous glucose monitoring (CGM) at 14–17 weeks, 20–23 weeks, 26–29 weeks, and 33–36 weeks. Key secondary outcomes were overnight time in target range, and time below glucose range (<3·5 mmol/L) overall and overnight. Analyses were conducted on an intention-to-treat basis. This trial is registered with ClinicalTrials.gov (NCT04520971). Findings: Between Jan 15, 2021 and Sept 30, 2022, 101 participants were screened, and 95 were randomly assigned to AHCL therapy (n=46) or standard insulin therapy (n=49). 43 patients assigned to AHCL therapy and 46 assigned to standard insulin therapy completed the study. At baseline, 91 (95·8%) participants used insulin pumps, and the mean HbA1c was 6·5% (SD 0·6). The mean proportion of time spent in the target range (averaged over four time periods) was 66·5% (SD 10·0) in the AHCL therapy group compared with 63·2% (12·4) in the standard insulin therapy group (adjusted mean difference 1·88 percentage points [95% CI –0·82 to 4·58], p=0·17). Overnight time in the target range was higher (adjusted mean difference 6·58 percentage points [95% CI 2·31 to 10·85], p=0·0026), and time below range overall (adjusted mean difference –1·34 percentage points [95% CI, –2·19 to –0·49], p=0·0020) and overnight (adjusted mean difference –1·86 percentage points [95% CI –2·90 to –0·81], p=0·0005) were lower with AHCL therapy than with standard insulin therapy. Participants assigned to AHCL therapy reported higher treatment satisfaction. No unanticipated safety events occurred with AHCL therapy. Interpretation: In pregnant women starting with tighter glycaemic control, AHCL therapy did not improve overall time in target range but improved overnight time in target range, reduced time below range, and improved treatment satisfaction. These data suggest that the MiniMed 780G can be safely used in pregnancy and provides some additional benefits compared with standard insulin therapy; however, it will be important to refine the algorithm to better align with pregnancy requirements. Funding: Diabetes Liga Research Fund and Medtronic. © 2024 Elsevier Ltd

Index Keywords
glucose, hemoglobin A1c; adult, age, Article, Belgium, clinical effectiveness, comparative effectiveness, continuous glucose monitoring, controlled study, female, gestation period, glucose blood level, glycemic control, human, hypoglycemia, insulin dependent diabetes mellitus, insulin treatment, intention to treat analysis, major clinical study, Netherlands, open study, outcome assessment, parallel design, patient care, patient satisfaction, pregnancy, pregnant woman, safety, treatment duration

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Publisher: Elsevier Ltd

ISSN: 22138587
PubMed ID: 38697182
Language of Original Document: English
Abbreviated Source Title: Lancet Diabetes Endocrinol.
2-s2.0-85193437878
Document Type: Article
Publication Stage: Final
Source: Scopus