Clinical evidence of high-risk medical devices for diabetes management: A systematic review and meta-analysis

To enable PROSPERO to focus on COVID-19 submissions, this registration record has undergone basic automated checks for eligibility and is published exactly as submitted. PROSPERO has never provided peer review, and usual checking by the PROSPERO team does not endorse content. Therefore, automatically published records should be treated as any other PROSPERO registration. Further detail is provided here.

Citation

Arjola Bano, Markus Laimer, Faina Wehrli, Juri Künzler, Christoph Stettler, Roman Hovorka, Lia Bally. Clinical evidence of high-risk medical devices for diabetes management: A systematic review and meta-analysis. PROSPERO 2022 CRD42022366871 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022366871

Review question

To evaluate the efficacy, safety and usability of high-risk medical devices used for the management of diabetes

Searches

We will perform literature searches using several databases including MEDLINE (Ovid), Embase (Elsevier), Cochrane Library (Wiley) CENTRAL, and Science Citation Index Expanded & Emerging Sources Citation Index (Web of Science). No restrictions will be imposed on time, language or publication period.

Types of study to be included

We will include:

(i) published studies of observational and experimental designs, including randomized controlled trials, non-randomized trials, cohort studies, case-control studies, cross-sectional studies, and case series; (ii) performed in humans.

We will exclude:

(i) Studies in animals, letters to the editor, proceedings, reviews, systematic reviews, meta-analyses, conference abstracts, case studies, errata, or expert opinion documents

(ii) Clinical investigations on medical devices that are not CE marked or not on a CE roadmap at the time of the search.

Condition or domain being studied

Diabetes management; Medical devices

Participants/population

Subjects with hyperglycemia or diabetes

We will include both pediatric and adult populations.

Intervention(s), exposure(s)

High-risk medical devices for diabetes management

Comparator(s)/control

Any comparator/control group (active intervention, sham-procedure, placebo or no intervention)

Main outcome(s)

The main outcomes for the review are efficacy, safety, and usability of medical devices.

Outcomes include:

1) Efficacy: metrics of glucose control, acute and chronic glucose-related complications

2) Safety: Severe hypoglycemia, diabetic ketoacidosis and other device-related Serious Adverse Events (SAEs)

• adverse device effects (ADEs):

• device deficiencies: malfunction, misuse and inadequate labeling

3) Usability

• technology acceptance

• patient-reported outcomes (PRO) measures for devices used for disease self-management

Additional outcome(s)

None

Data extraction (selection and coding)

This systematic review will be conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines for transparent reporting. Two independent reviewers will screen the titles and abstracts of the studies retrieved during the searches, and the full text articles of identified articles will be obtained and independently fully evaluated. Any disagreements regarding inclusion will be resolved through consensus. In case of disagreement, a third independent reviewer will be consulted. The full texts and reference lists of the selected articles will also be hand searched in order to identify additional studies for inclusion. Data extraction will be performed for each study using a predesigned data collection form, which will include the following information: article source, sample size, study design, demographics of study participants, intervention, comparator, outcome, study results and conclusions.

Risk of bias (quality) assessment

The quality of the included studies will be assessed separately by two reviewers. We will use the Newcastle-Ottawa Scale (NOS) for observational studies. We will assess the quality of interventional studies using a revised tool for assessing the risk of bias in randomized trials (RoB 2) and a tool for assessing the risk of bias in non-randomized studies of interventions (ROBINS-I).

Strategy for data synthesis

We will provide a narrative synthesis of the findings of the included studies.

Effect estimates will be reported in a summary table. Using descriptive statistics, we will report study characteristics, type of interventions and results for each device. We will assess potential differences across different study designs (i.e. observational studies versus randomized trials) across different classes of devices, and across different products in the same class of device. We will assess characteristics of the clinical studies that were available prior to the market release (CE marking) of the device and the evidence obtained post-market approval. If applicable, we will evaluate whether there are differences in the results when comparing men vs women, and younger vs older populations. The studies will be ordered by ascending year and we will evaluate whether the earliest published studies report sex or age differences more often than the subsequently published studies. Comparisons between independent groups will be performed with Fisher's exact, Mann-Whitney U, and Kruskal-Wallis tests, as appropriate.

If a meta-analysis is possible, the effect estimates will be pooled using random effects models, and forest plots will be constructed. Heterogeneity will be assessed by using the I^2 statistic, with $I^2 \leq 25\%$ considered as low, I^2 between 25% and 75% as moderate, and $I^2 \geq 75\%$ as high. The statistical analyses will be performed in Stata version 15.1 (StataCorp LLC, Texas, USA).

Analysis of subgroups or subsets

We will perform "leave-one out analysis" in order to evaluate the impact of individual studies on the overall results.

Contact details for further information

Arjola Bano

arjola.bano@ispm.unibe.ch

Organisational affiliation of the review

University of Bern

Review team members and their organisational affiliations

Dr Arjola Bano. University of Bern

Professor Markus Laimer. Bern University Hospital, Bern, Switzerland

Dr Faina Wehrli. University of Bern

Juri Künzler. Bern University Hospital, Bern, Switzerland

Professor Christoph Stettler. Bern University Hospital, Bern, Switzerland

Professor Roman Hovorka. University of Cambridge

Professor Lia Bally. Bern University Hospital, Bern, Switzerland

Collaborators

On behalf of . CORE-MD investigators

Type and method of review

Meta-analysis, Systematic review

Anticipated or actual start date

01 June 2022

Anticipated completion date

01 October 2023

Funding sources/sponsors

The project is supported by a grant from the European Union.

Grant number(s)

State the funder, grant or award number and the date of award

CORE MD, Grant Agreement 965246

Conflicts of interest

Language

English

Country

Switzerland

Stage of review

Review Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Diabetes Mellitus; Humans

Date of registration in PROSPERO

24 October 2022

Date of first submission

12 October 2022

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	Yes	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Versions

24 October 2022

24 October 2022