IQWiG Reports – Commission No. H21-01

Endoscopic duodenal mucosal resurfacing for type 2 diabetes

Addendum to commission H20-04[1]

Extract

[1] Translation of the executive summary of the addendum H21-01: *Endoskopische Thermoablation der Duodenalschleimhaut bei Diabetes mellitus Typ 2 – Addendum zum Auftrag H20-04* (Version 1.0; Status: 12 May 2021). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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Executive summary

In a letter dated 19 March 2021, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG), as an addendum to commission H20-04, to examine the conclusions of the assessment according to §137h Social Code Book (SGB) V on the benefit, harmfulness and ineffectiveness of the method "endoscopic duodenal mucosal resurfacing for type 2 diabetes".

Research question

The aim of the present investigation was to determine whether further relevant studies on endoscopic duodenal mucosal resurfacing (DMR) for type 2 diabetes exist besides the documents already used in the §137h assessment H20-04. If this was the case, it was to be examined whether, taking these into account, still neither a benefit, harmfulness nor ineffectiveness could be identified for the examination or treatment method in question. Furthermore, it was to be examined whether, besides the studies already used in the §137h assessment, ongoing studies exist that are in principle suitable to provide relevant findings on the benefit, harmfulness or ineffectiveness of the method in the near future.

Methods

Randomized controlled trials (RCTs) were to be included that investigated DMR for type 2 diabetes with regard to patient-relevant outcomes and had not already been used in the assessment according to §137h.

A systematic literature search for studies was conducted in MEDLINE, Embase, and the Cochrane Central Register of Controlled Trials. In parallel, a search for relevant systematic reviews was conducted in MEDLINE, Embase, the Cochrane Database of Systematic Reviews, and the HTA Database. The search was conducted on 16 February 2021. In addition, the following information sources and search techniques were considered: study registries and screening of reference lists. The selection of relevant studies was performed by 2 reviewers independently of one another.

Results

An additional publication to the Revita 2 study already used in the §137h assessment was identified in the information retrieval process. However, this did not contain any additional analyses that were not already available for the §137h assessment. Furthermore, no additional relevant completed or ongoing studies were identified that related to the present research question. Moreover, there is no new information on the currently ongoing RCT Revita-T2Di (NCT04419779) or the now completed RCT US-Pilot (NCT03653091) and we refer to the §137h assessment H20-04.

Conclusion

After systematic examination, there is still no evidence of a benefit, ineffectiveness or harmfulness of DMR for type 2 diabetes. Beyond the studies already considered in the §137h

assessment, no additional completed or ongoing studies were found that would in principle be suitable to provide evidence of a benefit, ineffectiveness or harmfulness in the near future.

The full report (German version) is published under

https://www.iqwig.de/en/projects/h21-01.html