LIPLEG study of the G-BA

The LIPLEG study is funded by the G-BA, the basis is the corresponding test guideline. The trial study is intended to answer the question of the benefits of liposuction in lipedema compared to a sole conservative, symptom-oriented treatment - in particular using complex physical decongestion therapy (KPE).

What is it about?

The Joint Federal Committee (G-BA) has commissioned a clinical study in which liposuction (operative liposuction) is to be compared with the standard non-operative treatment of lipedema. The costs of liposuction are borne by the statutory health insurance funds as part of the trial study. Based on the results of the study, the Joint Federal Committee will decide whether and under what conditions liposuction for lipedema will be paid for by the health insurance companies in the future.

How were the study participants determined?

The study can be participated in legally insured women with lipedema of the legs, in which there has not been sufficient relief from symptoms under conservative measures. The study is carried out at 11 study centers (clinics or practices) in Germany, about 450 women can participate. This website was given the opportunity to expression of interest via an online form. Since significantly more interested parties had registered than there were study places, a lottery procedure was carried out. All expressions of interest received by 31.12.2019 were taken into account in the draw for the participation places. The women identified in this way were then invited to an examination appointment.

The number of participants required for the study has now been reached. So no more women are contacted by a study center.

What is lipedema?

Lipedema is a painful, symmetrical, excessive multiplication of adipose tissue on the arms or legs. Lipedema occurs almost exclusively in women. A tendency to hematomas ("bruises") is typical even with small injuries. In addition, there may be increased water retention in the affected regions. The standard treatment is the so-

called complex physical decongestion therapy. It consists of the use of lymphatic drainage, compression by special stockings and exercise therapy. For some years now, doctors have also been offering surgical suction of the adipose tissue on the affected body parts (liposuction).

What do you know about liposuction?

In the case of stage I or II liposuction, liposuction is not yet a benefit of the statutory health insurance because there is no scientifically high-quality evidence that liposuction is more effective than the conservative standard treatment of lipedema from compression therapy, lymphatic drainage and exercise therapy. So it is not possible to say with certainty whether the women will be permanently relieved of their symptoms by the operation. For this, the two procedures must be compared directly with each other in two groups of patients.

The data on the long-term safety of liposuction in lipedema is also still insufficient. Thus, it cannot be ruled out that adipose tissue grows after liposuction or that the intervention in the subcutaneous connective tissue leads to scarring that hinder lymphatic drainage. These questions are to be examined in the study. In the presence of stage III lipedema, liposuction can also be available under certain conditions since 2020 as a benefit of the statutory health insurance funds. Your attending physician or Your doctor can tell you if this is right for you.

How does the study work?

If you have been contacted by a study centre as part of the draw procedure, the next steps are as follows:

- The doctor at the study center checks whether the inclusion criteria are met and whether there is no reason for exclusion for study participation. In principle, adult women with lipedema can participate in the study in all stages (I-III) in which conservative therapy measures have so far not led to any relief from symptoms. Further reasons for exclusion and exclusion are described in the study protocol.
- All women who are included in the study after the initial examination will initially receive physical therapy for about 7 months of compression treatment, possibly manual lymphatic drainage and exercise therapy.
- After the end of this preparation phase, a new examination takes place, in which the disease and the symptoms are collected.
- Two groups are now formed from all participants, which are to be compared with each other. This is done through a random procedure over which no one may have influence: The participants of one group, about 2/3, receive the liposuction treatment, possibly in several procedures. The participants of the second group, about 1/3, form the so-called control group, which receives physical therapy for another 12 months.
- 12 months after the last liposuction or after the additional 12 months of physical therapy in the control group, measured values are collected again for each patient, which are compared with each other at the end of the study.
- The women in the control group can then also receive liposuction if they still wish to do so.
- All women are then followed up for two more years, i.e. examined at certain intervals at the study center and asked about their well-being by means of questionnaires. This follow-up serves to identify possible late

effects of the procedure or the course of the lipedema.

- For each individual participant, a study participation takes a total of almost four years, in which multiple presentations at the study center are required. Not all women receive liposuction immediately as part of the study. About one third is initially (continued to) be treated conservatively and can, if desired, also be operated on at the earliest one year after group division.
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- It can be assumed that the study endpoint will be reached by the end of 2024.

Documents and links

› **to the LIPLEG study at the G-BA**