Incisional Negative Pressure Wound Therapy
Method to reduce the risk of wound infection in obese women following caesarean section

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Purpose
To investigate whether incisional Negative Pressure Wound Therapy (iNPWT) reduces the risk of wound complications in obese women following caesarean section, compared with standard dressing.

To date, this ongoing study is the largest randomised controlled trial worldwide investigating the effect of iNPWT on closed surgical incisions and the first of its kind examining the effect on post-caesarean incisions.

Methods
An unblinded, pragmatic, randomised multicenter trial, with 1:1 allocation. An electronic programme was used to allocate the participants into one of two groups (iNPWT vs. standard dressing), stratified by centre and type of caesarean section. The study is conducted at five public hospitals located in three regions of Denmark.

Population: Women with a pre-gestational BMI ≥30 undergoing planned or emergency caesarean section. The iNPWT or standard dressings is applied immediately following operation. In the intervention group the therapy will be left in situ for five days. In the control group the dressing will be left in situ for at least 24 hours as standard procedure. Post-operatively follow-up is after 30 days.

The primary outcome is wound infection. Secondary outcomes are other wound complications, contact with health services, and antibiotic treatment. Furthermore, an economic evaluation will be performed. Data are collected by an electronic questionnaire sent to the participants 30 days post-operatively. The data will be compared with data from medical records and national registers.

Interim analyses will be performed along the trial using the group sequential method. The analyses will be performed when sample size reaches 179, 357, 535, 713, and 891, respectively.

Inclusion started in September 2013, and is still ongoing. So far 450 participants have been included. The first interim analyses are about to be analysed. We expect to find a 50% reduction of wound infection when using iNPWT compared to standard dressings in this high-risk subpopulation.

Clinical experience shows that the iNPWT dressing reduces tissue oedema and remove haematoma. Overall the wound edges are in level and seem to be more healed when the iNPWT is removed after five day of treatment, compared to wounds being treated with standard dressing. Women treated with iNPWT generally experience less pain, and quicker mobilization compared to women in the control group.

Background
Obese women undergoing caesarean section have increased risk of surgical wound infection, which may lead to delayed recovery, pain, reduced quality of life, and increased health care costs.

The increased risk of wound infection may partly be explained by a decreased blood flow in adipose tissue and a local hypoxia response. In addition, adipose tissue can exert pressure on the wound edges, thereby decreasing the blood flow further and increasing the tissue forces at the incision line. By transmission of negative pressure to the wound, iNPWT increases the blood flow, reduces tissue oedema, decreases lateral and shears forces at the sutures, and increases lymph clearance.

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Fact box
• Worldwide, approximately 18.5 million caesarean sections are performed yearly.
• In the United States 32% of all deliveries were performed as caesarean sections in 2013. In the UK and in Denmark the similar caesarean rates were 26% and 22%, respectively.
• Caesarean deliveries involve major abdominal surgery and is one of the most important factors associated with postpartum infections. Obesity strengthens this association.
• In Denmark, the prevalence of overweight among women of reproductive age (16 to 44 years) reached 31.8% in 2013, and 11.6% were defined as obese (BMI> 30) (www.danskernessundhed.dk).
• Based on Danish data the expected baseline risk of wound infection is 10% in obese women giving birth by caesarean section.

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