

Att Lægemiddelstyrelsen
Kvalitetsevaluering og Kliniske Forsøg
Sektion Kliniske forsøg

Danish Medicines Agency
Medicines Licensing
Clinical Trials

Dear Section for Clinical Trials in the Danish Medicines Agency

Regarding the clinical study: "Fat Grafting with Ex-Vivo Expanded Adipose-Derived Stem Cells for Breast Reconstruction Following Mastectomy", Protokol no: 01062017, EudraCT nr.: 2016-005186-31.

The study group never initiated the above-mentioned clinical study (EudraCT nr.: 2016-005186-31), since our preliminary clinical trial showed no benefit of enriching fat transplants with adipose-derived stem cells compared to non-enriched fat transplants. (Previous study trial number: EudraCT-2014-000510-59)

We have published the results of our preliminary trial in a peer reviewed journal:

Peter V Vester-Glowinski, Mikkel Herly, Mathias Ørholt, Bo S Rasmussen, Felix C Müller, Jens J Elberg, Carsten Thomsen, Krzysztof T Drzewiecki, Fat Grafting With Expanded Adipose-Derived Stromal Cells for Breast Augmentation: A Randomized Controlled Trial, Aesthetic Surgery Journal, Volume 42, Issue 11, November 2022, Pages 1279–1289, <https://doi.org/10.1093/asj/sjac159>

Best regards

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