STUDY N.: LF-PB/14/05
EUDRACT N.: 2014-005289-31

A multicentre, double blind, randomized placebo controlled trial, to assess the effect of LF-PB on seroma formation in women with breast cancer undergoing Axillary Lymph Node Dissection

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Screening

CRF1
DATE OF VISIT

Date of Visit _____

INFORMED CONSENT

Date of Informed Consent Form _____

DEMOGRAPHY

Date of birth _____

Race

- ○ Caucasian
- ○ Black
- ○ Asian
- ○ Other

CRF2
INCLUSION CRITERIAS

1. Signed informed consent form
   - ○ Yes
   - ○ No

2. Female aged ≥ 18 years
   - ○ Yes
   - ○ No

3. Undergoing breast cancer surgery with axillary lymph node dissection during the current clinical trial
   - ○ Yes
   - ○ No

4. Negative serum pregnancy test for women of childbearing potential
   - ○ Yes
   - ○ No
   - ○ Not applicable

5. Aspartate aminotransferase and alanine aminotransferase < 2 x the upper limit of normal
   - ○ Yes
   - ○ No

6. Patients must have an Eastern Cooperative Oncology Group (ECOG) performance status ≤ 1
   - ○ Yes
   - ○ No

7. Compliant with the protocol requirements
   - ○ Yes
   - ○ No