

Press release

100,000 women with breast implants monitored for 10 years

In 2013 an estimated 346,000 women in France had breast implants. Some 30,000 of these are thought to have received an implant produced by the company PIP (some of which have since been removed). Beyond determining that these breast implants are defective, it appears that the only way to document their potential adverse effects is to conduct a large-scale epidemiological study. At the request of the Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM) [French National Agency of Medicine and Health Products Safety], a group of researchers managed by Florent de Vathaire in Inserm Unit 1018 "Centre for epidemiology and population health research" is launching a study entitled LUCIE. The aim of this 10-year study is to monitor some 100,000 women who have or have had breast implants of any brand. The results will enable conclusions to be drawn with regard to the potential medium and long-term adverse events in women with PIP implants.

In 2013, ANSM estimated that 346,000 women in France had silicone breast implants (either for aesthetic or medical reasons) including 30,000 with PIP brand implants. In explantations performed between 2001 and 2013, one in every four PIP implants explanted was considered defective. There are still uncertainties with regard to the long-term effects of these implants.

In order to examine the potential risk of these implants to the women who carry them, Inserm backed by the Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM) is launching a national epidemiology cohort study entitled LUCIE¹ with women who have or have had breast implants and have undergone surgery in France. The Inserm team managed by Florent de Vathaire of Unit 1018 "Centre for Research in Epidemiology and Population Health" will manage this study.

This cohort has been set up to evaluate and describe the incidence of adverse effects linked to silicone gel breast implants manufactured by PIP. The data collected will be used to determine the state of health of women who have had silicone gel breast implants and examine whether there is a link between any health events declared (breast cancer or other adverse effects such as allergic skin reactions or burst implants) and PIP breast implants.

The aim is to include approximately 100,000 women who have undergone breast implant surgery including 30,000 who currently have or have had a PIP implant (with the remaining implants produced by other manufacturers). To achieve this goal, the cohort will be recruited in two ways:

- 1) Through a transfer of records to Inserm researchers by hospitals and clinics which have implanted or explanted breast implants since 2001, regardless of the manufacturer.
- 2) Through voluntary registration of women after they have signed an on-line consent

¹ This name was chosen in reference to Lucy, the first known female ancestor who was long considered to be the origin of the human line of descent.

form on a "live" website on which they will be asked to complete an on-line questionnaire.

People who give their consent to take part will be contacted by e-mail every two to five years and asked to answer further on-line questionnaires (main health events which have occurred since they were last contacted, lifestyle etc.). The women are scheduled to be monitored for at least ten years.

Together, Inserm and ANSM are working to improve scientific knowledge of the problems associated with breast implants and therefore ensure that these products are used safely.



To help recruit and retain participants, Inserm researchers have taken the following steps to promote the study:

- A website to inform the public of progress with the study and disseminate results. Participants can access the on-line medical questionnaire via this website alarecherchedelucie.fr

- A campaign on social media (Twitter, Facebook, LinkedIn)

Twitter account [@EtudeLucie](https://twitter.com/EtudeLucie)

Page [Facebook](https://www.facebook.com/alarecherchedelucie): <https://www.facebook.com/alarecherchedelucie>

On [LinkedIn](#)

Any woman who has or has had breast implants can take part in this study even if she has not experienced any health problems. This is important for ensuring that the study is representative of people with silicone gel breast implants and will ensure that questions raised regarding breast implants are answered.

Women requiring further information can e-mail contact@cohorte-lucie.net or call the following number from 15 July:



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