Principal-Investigator :
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Project summary :

Facial Reconstructive surgery aims to restore the form and function of the face. Facial deformations have very deleterious psychological and sociological impacts, strongly altering patient's quality of life. At the Geneva University hospitals, an average of 50 patients per year need facial reconstructive surgery. Autologous adipose tissue grafting is extenslvelv used in facial reconstructive surgery. However, grafts are generally not stable with low vascularization and resorption rates ranging from 25% to 80%. A triple-blind, placebo-controlled clinical trial published in 2013 in the *Lancet* reported that addition of Adipose-derived Stem Cells (ASC) in fat grafts in the posterior part of upper arms of healthy volunteers strongly increased their stability and volume, without any side effects. However, the main limitation of ASC production in clinical-grade conditions is their low expansion and a progressive lack of their regenerative potential in culture. As this cell therapy has never been tested for facial reconstruction, we plan a clinical study for ASC-enriched fat grafting in the context of congenital malformations and after traumas. Regarding the simplicity of the concept combined with the availability of clean rooms for clinical-grade cell productions, we propose a starting collaboration between the reconstructive surgery unit (department of surgery) and the laboratories of experimental cell therapy (department of genetic, laboratory medicine and pathology) to produce clinical-grade ASC to be added to fat grafts. The goal of this project is to (i) increase the expansion and regenerative potential of ASC in culture through their maintenance in small 3D tissues, in a rnedla supplemented by platelets-rich plasma (PRP) (ii) produce clinical-grade ASC upon Good Medical Practice (GMP) conditions to prepare a phase I clinical study evaluating their interest for facial reconstruction.

Goals and milestones

Before the end of the first yaer of funding

- Several ASC cultures has been derived from adipose tissue in animal-free and chemically defined conditions according a clinical grade-comptable protocol.
- Improvement of ASC expansion and regenerative potential has been achieved through 3D culture conditions and addition of platelets-rich plasma.
- The regenerative potential of ASC has been tested in vitro and in vivo by using an animal model of fat grafting.
- The tumorigenic potential of ASC has been evaluated in vivo by using an animal model of xenotransplantation.
- The protocol for ASC production has been transferred to clean rooms and adapted to Good Manufacturing pratice (GMP) conditions, with the goal to prepare a phase I clinical study.