Full title	Mesenchymal stromal cells treatment in Lyell syndrome:
	A pilot phase 1-2 open trial.
Acronym	LYSYME
Loordinating	Saskia Oro
Investigator	Hospital Hanri Mondor
Sponsor	Assistance Publique – Hônitaux de Paris
Scientific justification	Stevens-Johnson syndrome (SIS) and toxic enidermal necrolysis (TFN) are rare
Scientific Justification	acute life-threatening muco-cutaneous drug-adverse reactions.
	To date, no curative treatment has demonstrated its ability to promote SIS-TEN
	healing. MSCs, combining their immunomodulation effects and secretion of soluble
	factors implicated in wound repair, are a promising cell therapy strategy for
	promoting cutaneous healing in SJS-TEN syndrome and decrease the morbi-
	mortality.
Primary objective and	To evaluate the safety and efficacy i.e., complete almost complete cutaneaous
outcome	reepithelialisation at D7 after infusion of 2×10^6 /kg ASCs in SJS-TEN patients.
	• <u>Safety:</u> The toxicity is defined as the observation of at least one adverse
	• Efficacy: Pate of complete almost complete reepithelialisation at D7 after
	infusion.
	This criterion is defined as at least 90% of cutaneous body surface area
	(BSA) healed at D7 in comparison to maximal cutaneous detachable-
	detached BSA observed.
Secondary objectives	To evaluate the impact of ASCs treatment on SJS-TEN clinical course and
and outcomes	immunological markers.
	- Rate of observed and predicted death at one month by the SUORTEN
	involved onset of the disease and SCORTEN
	- Duration of each mucous membrane healing i.e. (buccal, nasal, genital, eyes).
	- Rate of sepsis.
	- Rate of intensive care transfer
	- Rate of sequelae at M12
	- Th1/Th2 immune response in the peripheral blood of the patients after
	injection at D0, D10, M1
	- Evaluation of expression profile of 1n1/1n2 associated chemokines and anti- inflammatory chemokines in the peripheral blood after injection at D0 D10
	M1.
	- Epidermal chimerism research on healed skin biopsy at 1 month.
	- Rate of complete almost complete reepithelialisation at D5, D10 and D15 after
	infusion.
Experimental design	Single hospital open label phase 1-2 trial assessing the tolerance and efficacy of
	2×10^{6} /kg of ASCs intravenously injected at D0 in patients with more than 10%
	detached-detachable body surface area.
Population of research	Patients: Adults diagnosed with SIS TEN with at least 10% of hody surface area
narticinants	involved
Puriopuno	Donors: Adults selected for a programmed plastic surgery of liposuction or
	aspiration in the abdominal wall under general anesthesia, in order to collect
	adipose tissue
Inclusion criteria	Patients:
	 Patients ≥ 18 years-old
	- Admission less than 10 days after onset of the reaction
	- ratient with confirmed SJS-TEN diagnosis nospitalized in the department of
	- At least 10 % of detachable-detached hody surface area at any time during the
	first 10 days after the index date
	- Written consent from patient or trustworthy person or legal representant or
	family member

Donors: Patients 2 18 years-old Admission for a programmed plastic surgery of liposuction or aspiration in the abdominal wall under general anesthesia Selection criteria according to stem cell donor health history questionnaire from Agence de la Biomédecine Written consent Affiliated to a social security scheme Exclusion criteria Pregnant or breastfeeding women History of malignant disease within the past ten years and or presence of metastasis Positive serology for HV Active infection for hepatitis B or C Patient deprived of freedom Any psychological, familial, sociological or geographical condition potentially hampering compliance with the research protocol and follow-up schedule Denors: Positive schological, familial, sociological or geographical condition with IgM+ for toxoplasmosis, EBV, CMV) Deprived of freedom Significant comorbidities (according to stem cell donor health history questionnaire from Agence de la Biomédecine) Investigational medicinal product(s) Single Dose injected: 2x10 ^o /kg injected intravenously at maximum three days after admission Phase I-11 Comparator treatment Supportive standard care Interventions addef or folgo of adipose tissue for research, during the liposuction carried out in the usual's care </th <th></th> <th> Affiliated to a social security scheme </th>		 Affiliated to a social security scheme
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Practical	Donors will be selected among those coming for liposuction or aspiration in the
implementation	abdominal wall.
	ASCs will be expanded from several allogeneic donors and qualified in Good
	Manufacturing Procedures conditions by the Creteil GMP platform (EFS Ile de
	France).
	After inclusion of the patient, ASCs will be thawed and culture in GMP conditions
	following 24 hours in order to restore the immunosuppressive properties of MSCs.
	ASCs intravenously injected 3 days after inclusion in patients with more than 10%
	detached-detachable body surface area.
Number of participants	Patients: 15 subjects (please see sample size section for more details)
included	Donors: 5
Number of centres	National pilot research with participation of multicentric sites at hospital Henri- Mondor (reference center of toxic bullous diseases)
	with 4 hospital services:
	 Department of Dermatology and Intensive Care Unit for patients;
	- Plastic surgery and CIC for donors
Research duration	Inclusion period: 36 months
	Length of participation (<i>treatment 1 day + follow-up</i>): total 12 months
N-mhar of inclusions	Total research period: 48 months
ovported per contro and	0.4 patient per month
ner month	
Statistical analysis	The primary efficacy and safety endpoints will be analyzed using a Bayesian
Statistical analysis	strategy. It provides a formal means of summarizing patient outcome by a single
	binary event (Toxicity or not, success or failure). It will allow continuous monitoring
	of outcomes throughout the trial and thus was expected to be more efficient in
	protecting patients from unsafe treatment. The efficacy endpoint will also be
	analyzed through a Bayesian strategy taking into account gain functions based on
	population cost regarding overall treatment success (see sample size section)
Funding source	The research is funded by a grant from Programme Hospitalier de Recherche Clinique - PHRC 2015 (Ministère de la Santé)
Data Safety Monitoring	Yes
Board anticipated	