Full title	Multicentric prospective study assessing the efficiency of preoperative reversible selective portal vein embolization in patients requiring major hepatic resection
Acronym	EMBORES
Coordinating Investigator	Ibrahim DAGHER Department of minimally invasive digestive surgery Antoine Béclère hospital, Clamart Email: Ibrahim.dagher@abc.aphp.fr
Scientific Director	Hadrien TRANCHART Department of minimally invasive digestive surgery Antoine Béclère hospital, Clamart Email hadrien.tranchart@abc.aphp.fr
Sponsor	Assistance Publique – Hôpitaux de Paris
Scientific justification	Portal vein embolization (PVE) is used before major hepatectomy, to induce hypertrophy of the future liver remnant (FLR). A non-absorbable material is generally used for embolization, as it provides effective, permanent vascular occlusion. Our team has developed a minimally invasive technique of reversible PVE using gelfoam powder. The aim of this study is to assess the tolerance and efficiency of preoperative reversible selective PVE in patients requiring major hepatic resection.
Primary objective and assessment criterion	To demonstrate that preoperative reversible PVE allows to similarly increase FLR volume in comparison with classical non-absorbable PVE in patients requiring major liver resection with limited FLR. Primary End Point: Hypertrophy ratio of FLR volume / total liver volume evaluated by computed tomography scan 4-6 weeks after PVE
Secondary objectives and assessment criteria	To show benefits (related to PVE): Technical feasibility, Morbidity, Portal recanalization, Performing planned surgical procedure To show benefits (related to hepatectomy): Per and postoperative morbidity Secondary End Points: Embolization: Percentage of completed PVE; Per and post procedure morbidity, Rate of portal recanalization, Rate of major liver procedures Hepatectomy: Inflammation and adhesions during portal pedicles dissection, Intra and postoperative morbidity
Experimental design	Single-arm feasibility study
Inclusion criteria	- patient aged between 18 and 80 years - informed written consent - patient requiring major liver resection - PVE indication decided in a multidisciplinary meeting
Non-inclusion criteria	- American Score of Anesthesiologist (ASA) ≥ 3 - portal vein or hepatic vein thrombosis - associated (6 weeks before or after PVE) percutaneous liver treatment - pregnancy or breast feeding - patient not covered by social security service - patient under guardianship
Practical procedure	Percutaneous access to the portal vein is achieved under moderate sedation with ultrasound and fluoroscopic

	control. After assessment of portal venous anatomy, embolization of selected portal vein segments is performed using the powdered form of an absorbable gelatin sponge.
Number of subjects chosen	50
Number of centres	National study involving 7 centers
Research period	Anticipated Duration of Recruitment: 18 months Duration of participation of each patient: 12 months Total duration of study: 30 months
Number of inclusions expected per centre and per month	0.5 patients/ month / center
Data Safety Monitoring Board anticipated	Yes

Full title	Multicentric randomized prospective study assessing the impact of the bougie calibration size during laparoscopic sleeve gastrectomy on the rate of postoperative staple-line leak rate
Acronym	BOUST
Coordinating Investigator	Hadrien TRANCHART Department of minimally invasive digestive surgery Hospital Antoine Béclère, Clamart Email: hadrien.tranchart@abc.aphp.fr
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Sponsor	Assistance Publique – Hôpitaux de Paris
Scientific justification	Laparoscopic sleeve gastrectomy (LSG) has become an increasing bariatric procedure. The most common complication is gastric leak from the staple line, observed in approximately 3% of cases, and can result in long and incapacitating treatment. The diameter of the bougie used to calibrate the remnant stomach could impact the rate of gastric leak, a higher diameter being correlated with a lower risk of leak, without lowering long-term weight loss. The aim of this prospective randomized trial is to compare the outcomes of LSG according to the use of a bougie calibre of 36 or 48-Fr on postoperative gastric leak and mid-term weight loss.
Primary objective and assessment criterion	To demonstrate that usage of a 48-Fr calibre bougie during LSG is associated with a decreased postoperative gastric leak rate compared with usage of a 36-Fr bougie. Primary End Point: postoperative leak rate during the first month following the procedure
Secondary objectives and assessment criteria	To assess the impact of bougie diameter on: - Postoperative morbidity - Short-term weight loss - Mid-term weight loss - Short- and mid-term quality of life - Consumption of economic resources
Experimental design	Double Blind Randomized clinical trial
Inclusion criteria	- Patient age between 18 and 70 years - Sleeve gastrectomy as a primary bariatric procedure (cholecystectomy excepted) - Body Mass Index (BMI) > 40 kg/m² or > 35 kg/m² associated with at least one comorbidity susceptible to improve after surgery - Decision for intervention after multidisciplinary discussion - Written informed consent
Non-inclusion criteria	- Previous upper abdominal surgery - ASA (American Society of Anesthesiologists) score > 3 - Ongoing pregnancy or breast feeding - Patient not covered by social security service - Patient under legal guardianship - Patient with known latex allergy
Risks added by the research	B

Practical procedure	Sleeve gastrectomy is performed with the standard procedure. After randomization, bougie is placed before gastric section.
Number of subjects chosen	1658
Number of centres	23 centres (national)
Research period	Anticipated Duration of Recruitment : 24 months Duration of participation of each patient : 24 months Total Duration : 48 months
Number of inclusions expected per centre and per month	3
Statistical analysis	Randomisation 1:1 according to minimisation technique. Stratification will be carried out relating to centre, gender, and BMI > 50 kg/m² Intermediate analysis will be fulfilled when half of patients has been included.
Data Safety Monitoring Board anticipated	No