

HEPATEX: encapsulated hepatocytes for temporal liver replacement

The Challenge

In Spain, over 5500 liver transplants have been successfully performed in 2019 with an approximate cost of €44M. Although remarkable, the annual number of organ transplants cover less than 10% of the needs. **Over 200 patients die while waiting for transplant.** This represents an underestimation. Cirrhosis and liver cancer are the latest stage of liver disease, regardless from the aetiology. The only available treatment is getting a new liver prior the multiorgan failure occurs. **This technology has the potential to improve the patient condition during the waiting time and avoid those deaths.**

The Market

HEPATEX can represent a liver replacement therapy for end stage liver disease patients until an appropriate liver donation is available. The liver disease treatment market is anticipated to chart an impressive growth trajectory over the forecast period from 2020 to 2030. Surge in the number of liver diseases, along with unmet clinical needs for liver diseases are some primary factors boosting the liver disease treatment market. Vast scope of clinical research for improvement in existing line of treatment, and new therapeutics for liver diseases are expanding the growth horizon of liver disease treatment market.

The Asset

HEPATEX represents a temporal replacement of transplantation using **injectable bio-printed micro-spheroids containing functional liver cells** wherein collagen is used to generate two-layer capsules through different cross-linking methods. These human liver micro-spheroids are generated from the isolation of human cells from discarded liver. The size of these micro-liver ranges from nanometer to micrometer making suitable for intravenously injection. **The encapsulation allows: i) cell protection; ii) cell confinement; iii) normal diffusion of nutrients and oxygen and exchange with the body.** Since the main component of the bio-ink is collagen, the most abundant proteins in the body, the material mimics the native organ environment and allows the cell to survive and function over long period. **Furthermore, they generate a negligible immune response from the host.** A robust 3D bioprinting platform can fabricate 80 liver micro-spheroids per minute that contain up to 3 million liver cells in a total sterile environment.

The asset value

- *Cost-effectiveness.* Our 3D bioprinter fabricates 80 spheroids/minutes using human collagen and liver cells from discarded organs. The cost is approximately €0.80 per spheroid.
- *Scalability.* The entire production process can be automated where the manual input from operator, and the associated errors, are minimised.
- *Versatility.* Our bioink can encapsulate different cell types such as pancreatic and skeletal muscle cells.
- *Safety.* Our protocol did not require any genetic manipulation of the cells (i.e., CRISPR-cas9).
- *Consistency.* Our bio-ink formulation is consistent throughout all the development process ensuring negligible variability among different batches.

Novel hydrogel capsule for allogenic liver cell delivery for treatment of Liver diseases.

This method protects the cells to reach the liver safely while adding hepatic function



Uses

- Improvement liver function in patients in waiting list for liver transplant.
- Treatment of hepatic diseases
- Companion diagnostics and prognosis in vitro method
- Different cell types can be encapsulated as pancreatic and skeletal muscle cells.

Scientific Project Leader

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<https://ibecbarcelona.eu/biosensors>

Stage of development

TRL3 - The technology is fully validated in the laboratory and a preliminary safety test in pre-clinical model has been done. It is ready to be more extensively tested in preclinical disease models to assess efficacy in liver functions supply, biomaterial's mechanical properties and cell delivery.

Intellectual Property Status

WO2021048250A1, PCT application filed in Sept 2020, the patent application has entered National Phase in EU and US. Possibility to extend the protection to other territories.

Exploitation plan

Patent available for licensing with technical cooperation / Technical co-development

Contact

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