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Celsior versus University of Wisconsin preserving solutions for liver transplantation

Submission date 31/05/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/07/2009	**Overall study status** Completed	
Last Edited 21/07/2009	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI07/49

Study information

Scientific Title

Celsior versus University of Wisconsin preserving solutions for liver transplantation: a prospective randomised controlled study

Study objectives
Celsior solution offers the same degree of safety and effectiveness as University of Wisconsin solution for liver transplantation.

Celsior solution is a high-sodium, low-potassium, and low-viscosity extracellular solution used for liver graft preservation. University of Wisconsin solution, an intracellular solution with high potassium content, has been universally accepted as the standard for the perfusion and storage of cold hepatic grafts.

The results of the pilot study have been published in 2003: http://www.ncbi.nlm.nih.gov/pubmed/12884193

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee of Aragon approved on the 17th October 2007 (ref: PI07/49)

Study design
Interventional single-centre prospective open-label randomised active-controlled two-arm parallel assignment phase IV trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Liver transplantation

Interventions
1. Celsior preservation solution (experimental):
N = 51 adult transplant recipients. Donor liver recovery was performed using conventional multi-organ procurement techniques. Celsior preservation solution cooled to 4°C was perfused by gravity through the aorta (4 L) and portal vein (2 L) in situ and on the back table through the portal vein (1 L). After recovery, the grafts were kept at 4ºC in conventional bags containing Celsior solution until transplantation. The liver transplant was performed preserving the

retrohepatic vena cava (piggyback technique) without venovenous bypass. Before reperfusion, the graft was washed through the portal vein with 1200 ml cold Ringer's lactate. Reperfusion of the grafted liver was followed by hepatic arterial and biliary reconstruction. Total duration of follow-up: five years.

2. University of Wisconsin preservation solution (active comparator):
N = 51 adult transplant recipients. Donor liver recovery was performed using conventional multi-organ procurement techniques. University of Wisconsin preservation solution cooled to 4°C was perfused by gravity through the aorta (3 L) and portal vein (2 L) in situ and on the back table through the portal vein (1 L). After recovery, the grafts were kept at 4ºC in conventional bags containing University of Wisconsin solution until transplantation. The liver transplant was performed preserving the retrohepatic vena cava (piggyback technique) without venovenous bypass. Before reperfusion, the graft was washed through the portal vein with 1200 ml cold Ringer's lactate. Reperfusion of the grafted liver was followed by hepatic arterial and biliary reconstruction. Total duration of follow-up: five years.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Celsior preserving solutions, University of Wisconsin preserving solutions

Primary outcome measure
1. Intra-operative mortality. Time Frame: intervention day.
2. Post-reperfusion syndrome. Time Frame: Intervention day. Post-reperfusion syndrome was defined as a decrease in the mean arterial pressure of more than 30% of the baseline value for more than one minute during the first five minutes after graft reperfusion. In relation to post-reperfusion syndrome, 17 intra-operatory variables were analysed, eight haemodynamic and nine metabolic. These variables were heart rate, mean arterial blood pressure, central venous pressure, mean pulmonary artery pressure, pulmonary capillary wedge pressure, cardiac output, systemic vascular resistance index, pulmonary vascular resistance index, central body temperature, arterial pH, standard bicarbonate, base excess, serum sodium, serum potassium, ionised calcium, magnesaemia, and glycaemia.
3. Primary non-function or primary dysfunction graft. Time Frame: first week post-liver transplantation. Primary non-function defined as the acute failure of the transplanted liver, leading to re-transplantation or death within seven days of the initial procedure, with no identifiable cause of graft failure. Primary dysfunction was defined as the elevation of transaminases 30-fold above normal and a prothrombin time greater than 20 seconds maintained for 3 days in the first week post-LT
4. Mortality during the first 30 days post-liver transplantation. Time Frame: 30 days post-liver transplantation.
5. Liver re-transplantation and causes. Time Frame: Five years post-liver transplantation.
6. Graft and patient survival during the follow-up period. Time Frame: 5 years post-liver transplantation.

Secondary outcome measures
1. Days in the Intense Care Unit. Time Frame: first 15 days post-liver transplantation.
2. Rates of acute rejection. Time Frame: Five years post-liver transplantation. Acute cellular

rejection was proven by percutaneous liver biopsy.
3. Rates of chronic rejection. Time Frame: Five years post-liver transplantation. Chronic rejection was proven by percutaneous liver biopsy.
4. Infectious complications. Time Frame: Five years post-liver transplantation.
5. Vascular and biliary complications. Time Frame: Five years post-liver transplantation.
6. Values of aspartate aminotransferase (AST), alanine aminotransferase (ALT), gamma-glutamyltransferase (GGT), bilirubin, and prothrombin activity. Time Frame: first 5 days post-liver transplantation.

Overall study start date
01/01/2001

Completion date
31/12/2003

Eligibility

Key inclusion criteria
1. Adult liver transplant recipients
2. Minimum age: 18 years, maximum age: 70 years
3. Both sexes

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
102 adult transplant recipients

Key exclusion criteria
Grafts procured in other centres by different surgical teams

Date of first enrolment
01/01/2001

Date of final enrolment
31/12/2003

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Clínico Universitario Lozano Blesa
Zaragoza
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50009

Sponsor information

Organisation
Aragon Health Science Institute (Spain)

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Sponsor type
Government

ROR
https://ror.org/031n2c920

Funder(s)

Funder type
Government

Funder Name
Aragon Health Science Institute (Spain)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2006		Yes	No