ISRCTN65689096 https://doi.org/10.1186/ISRCTN65689096

Comparison of two techniques for collecting umbilical cord blood: on the mother (upper level) versus on the delivery table (bottom level)

Submission date	Recruitment status	[X] Prospectively registered
07/10/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/11/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/11/2010	Pregnancy and Childbirth	[ ] Record updated in last year

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
N/A

Study information

Scientific Title
A randomised controlled clinical trial of the comparison of two techniques of umbilical cord blood collection (from mother versus on delivery table) on women with term pregnancy with low-risk vaginal delivery and a unique newborn

Study objectives
The collection of umbilical cord blood (UCB) clamped on the mother is more effective since it achieves a greater amount and cellularity of UCB units with no increase in cross-clamping time compared to clamping on the delivery table.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee of Guipuzcoa Health Area approved on the 21st June 2010 (ref: 6/10)

Study design
Randomised controlled clinical 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
Umbilical cord blood collection

Interventions
Control group:
Clamping and cutting the umbilical cord blood on lower level about introitus, placing the newborn at delivery table (the table is about 80 cm from the introitus of the mother).

Experimental group:
Clamping and cutting the umbilical cord blood on upper level on the mother's abdomen.

Measured at collection after delivery; no follow up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Weight of cord blood units, quantitative variable, measured in mg. Outcomes will be measured simultaneously with the intervention.

Secondary outcome measures
Validity of the unit and storage. Validity criteria are considered:
1. If the count is 1.5 x 10^9 TNC unit is accepted
2. If the count is between 1.2 and 1.5 x 10^9, CNT is performed CD34 count, if this is greater than 4 x 10^6 units is accepted

Outcomes will be measured simultaneously with the intervention.

Overall study start date
01/12/2010

Completion date
01/02/2011

Eligibility

Key inclusion criteria
1. Term pregnancy
2. Low-risk vaginal delivery
3. Unique newborn
4. Maternal age greater than 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
44

Key exclusion criteria
1. Maternal age less than 18 years
2. Mental instability, intoxication by alcohol or narcotics
3. Have or have had: hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), human T-lymphotropic virus type I and II (HTLV I/II), babesiosis, kala-azar, and Chagas

disease
4. Exposure to the risk of a transmissible infection:
4.1. For transfusion: Ineligible for six months (or for four months, if the screening test for hepatitis C virus using genomic technology of nucleic acid-NAT-negative results). Exclusion of people with a history of being transfused in the UK or malaria-endemic countries, HTLV, Chagas disease, HIV.
4.2. Tattoo or piercing the skin or mucous membranes, in the last six months (value)
4.3. Acupuncture in the six months preceding the birth, except done with sterile needles and by a qualified professional
4.4. People at risk due to direct household contact or sexual intercourse with people suffering from hepatitis, in the last six months
4.5. Instrumental-flexible endoscopy. Examinations or treatments involving the use of central catheters have been placed for several days in the last six months.
4.6. Splash of blood or mucus needle injury in the last six months
4.7. Major surgery in the past six months
5. Drug: intravenous or intramuscular non-prescription, including steroid or hormonal treatment for increased fitness
6. People who practice or have practiced prostitution
7. Sexual behaviour: exclusion of persons whose conduct is at high risk of serious infectious diseases transmitted through blood and blood components. After the cessation of risky behavior should be excluded for 12 months minimum.
8. Persons under xenotransplantation (organs of other animal species)
9. Cancer: Presence or history of malignancy (except basal cell carcinoma from primary skin carcinoma in situ of the uterine cervix, and some primary cntral nervous system [CNS] tumours, to be properly evaluated)
10. Patients with congenital coagulation disorders treated with blood products of human origin (clotting factors), any deficit inherited granulocytes, platelets, leukocytes, and hereditary enzyme, thrombocytopenia, alterations in the white series, treatment with oral anticoagulants or hereditary spherocytosis
11. Risk of transmission of prion diseases:
11.1. People with a diagnosis or family history of Creutzfeldt-Jakob disease and variant Creutzfeldt-Jakob disease
11.2. Receptors derived from human pituitary hormones (e.g., growth hormone), dura mater recipients, recipients of cornea, sclera or other eye tissue
11.3. People with a history of dementia or degenerative neurological diseases caused by viral infection or unknown
11.4. People with more than 12 months stay in the United Kingdom during the period 1980 - 1996
12. Exclude during and at least two weeks after complete clinical recovery of an infectious disease, except for infections that are listed below where the following criteria apply:
12.1. Brucellosis, two years after complete restoration
12.2. Osteomyelitis: two years after cure confirmed
12.3. Q-fever: two years after cure confirmed
12.4. Syphilis: one year after cure confirmed
12.5. Toxoplasmosis: six months after clinical recovery
12.6. Tuberculosis: two years after cure confirmed
12.7. Rheumatic fever: two years after the disappearance of symptoms, unless there is evidence of chronic heart condition
12.8. Flu-like condition in two weeks after symptoms disappear
12.9. Maternal fever above 38°C, two weeks after his disappearance
13. Diseases of unknown aetiology, e.g., Parkinson's disease, Multiple Sclerosis, Amyotrophic lateral sclerosis (ALS), Crohn's disease, ulcerative colitis, ischaemic colitis, pancreatitis, and autoimmune diseases or connective tissue (systemic lupus erythematosus, rheumatoid arthritis,

etc.)
14. Diabetes (type I and II), diabetes insipidus, pituitary insufficiency, pituitary adenoma, thyroid adenoma, Graves disease, Hashimoto's thyroiditis, hyperparathyroidism, adrenal insufficiency, congenital adrenal hyperplasia, Cushing, hyperaldosteronism, pheochromocytoma, hyperlipaemic essential hyperthyroidism and hypothyroidism pharmacological treatment
15. Extensive psoriasis, bullous dermatitis, erythema nodosum, mycosis fungoides, Bechet's disease, dermatitis herpetiformis, Sezary disease, Recklinghausen, etc.,
16. Viral pericarditis in the past six months
17. Vaccination:
17.1. Attenuated virus and bacteria: exclusion for four weeks
17.2. Virus, bacteria or rickettsiae inactivated or eliminated: no exclusion of healthy people
17.3. Toxoids: no exclusion of healthy people
17.4. Vaccines against hepatitis A or hepatitis B: no exclusion of healthy people not exposed (accidental puncture)
17.5. Rabies: no exclusion of healthy people not exposed. Be excluded for one year if the vaccine is administered after exposure.
17.6. Vaccination against tick-borne encephalitis: no exclusion of healthy people not exposed
18. Exclusion epidemiological situations
19. Malaria:
19.1. People who have lived in a swamp during the first five years of life are excluded three years after the return of last visit to the endemic area, as long as no symptoms. The exclusion period can be reduced to four months if an immunologic or genomic molecular test validated for diagnosis of malaria is negative.
19.2. People with a history of malaria, will be excluded for three years after discontinuation and absence of symptoms. Subsequently, these people may be admitted if a molecular or genomic immunoassay validated for diagnosis of malaria is negative.
19.3. People without symptoms who have visited endemic areas, are excluded for six months after leaving the endemic area, unless a molecular or genomic immunoassay validated for diagnosis of malaria is negative
19.4. People with a history of undiagnosed febrile illness during a visit to an endemic area or within six months, will be excluded for three years after the disappearance of symptoms. May be reduced to four months if an immunologic or genomic molecular test validated for diagnosis of malaria is negative.
19.5. West Nile Virus: exclusion for 28 days after leaving an area where cases are detected transmission to humans
20. Maternal history and/or paternal genetic disease known
21. Severe maternal anaemia (haemoglobin less than 10 g severe)
22. Duration of less than 37 weeks gestation
23. Presence of symptoms of infection in the newborn
24. Clinical signs of foetal-maternal haemorrhage
25. Neonatal weight less than 2500 g
26. APGAR less than 8 with a poor outcome after 10 minutes
27. Signs of meconium aspiration by the infant
28. Maternal fever above 38°C during labour
29. Maternal hypertension
30. In pregnancies resulting from donated eggs or sperm, the donation will be excluded unless the genetic history of biological parents was obtained and documented
31. The administration of anti-D in the last 12 months is not grounds for exclusion, but must register
32. Disease with limited delivery of the extraction procedure
33. The relevant conditions existing in the parents and siblings should be reviewed

Date of first enrolment
01/12/2010

Date of final enrolment
01/02/2011

Locations

Countries of recruitment
Spain

Study participating centre
Balleneros 6-3 D
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20011

Sponsor information

Organisation
Hospital Donostia (Osakidetza) (Spain)

Sponsor details
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20014

Sponsor type
Hospital/treatment centre

Website
http://www.osakidetza.euskadi.net

ROR
https://ror.org/04fkwzm96

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital Donostia (Osakidetza) (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