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Study of the efficacy and safety indicators of two different iron chelators in patients with iron overload (Estudio de los indicadores de eficacia y seguridad de dos quelantes del hierro en pacientes con sobrecarga ferrica)

Submission date	Recruitment status	[ ] Prospectively registered
31/01/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/04/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/04/2011	Haematological Disorders	[ ] 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
TRA-158 (EC09/080)

Study information

Scientific Title
A single-centre, prospective, randomised, phase III clinical study to evaluate the efficacy and safety indicators of two different iron chelators in patients with iron overload

Acronym
QuelaFer

Study objectives
The main aim of this study is to evaluate the efficacy of Deferasirox versus Deferoxamine in reducing serum ferritin levels and iron liver deposits in iron overload patients.

Excess iron in blood and tissues causes irreversible tissue damage. The removal of excess iron as response to treatment positively influences on the survival of patients with overload. Currently, there are two types of iron chelating agents authorised, each one with different route of administration (Deferoxamine-parenteral and Deferasirox-oral) but the superiority of one over another is not defined in relation to the intensity of the response, time to be reached or the severity and frequency of associated adverse effects or its impact on quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee of Aragon (Comité Ético de Investigación Clínica de Aragón) (CEICA).
Ref: C.I. EC09/080 11/08/2010

Study design
Phase III single-centre prospective randomised clinical study

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
Haemosiderosis

Interventions
1. Group A: Deferasirox 20 mg/kg/day oral capsules for 4 months
2. Group B: Desferoxamine 30 mg/kg/day, slow Subcutaneous (SC) infusion administered over 8 hours by a portable infusion pump 3 times/week for 4 months
3. Patients from both groups will be followed for 1-month period.
4. The following tests should be performed:
4.1. Peripheral blood creatinine (weekly in the 1st month and then monthly), serum transaminases, bilirubin and alkaline phosphatase (on day 1 of treatment, every 2 weeks in the 1st month, then monthly, and at the end of treatment)
4.2. Serum ferritin (at screening, at baseline and at the beginning of each month of treatment)
4.3. Liver magnetic resonance imaging (MRI) and quantification of tissue iron (at screening visit and at the end of 4 months of treatment)
4.4. Computerised tomography (CT), CCL18 and proBNP activity (at screening, before the 2nd month of treatment and after treatment)
4.5. Eastern Cooperative Oncology Group (ECOG) performance status (at screening, and on day 1 of each new cycle of treatment)
4.6. Electrocardiogram (at screening and whenever the investigator deems it appropriate, SF36 quality of life questionnaire (at screening, before the 2nd month of treatment and after treatment).

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
1. Deferoxamine 2. Deferasirox

Primary outcome measure
Treatment efficacy was determined by measuring the serum ferritin at screening, at baseline and at the beginning of each month of treatment

Secondary outcome measures
1. Identify whether blood biomarkers of macrophage activation (chitotriosidase, CCL-18) are higher in patients with iron overload than in the population with normal serum ferritin levels stratified by age and sex and if they can be used as markers of response to chelation therapy
2. To study if the biomarkers concentration correlates with the serum ferritin level, liver MRI, cardiac function assessed by ultrasound and its own changes after 4-month treatment with iron chelators
3.To assess the quality of life of patients undergoing both these treatments

Overall study start date
01/03/2011

Completion date
30/09/2012

Eligibility

Key inclusion criteria
1. Age ≥ 18 years
2. Diagnosis of myelodysplastic syndrome
3. Have received a hematopoietic stem cell transplantation in the last 6 months
4. Gaucher's disease diagnosis
5. Serum ferritin concentration >500 mcg/L
6. To not have received previous iron chelation therapy
7. No severe renal failure (creatinine clearance >30 ml/min/1.73 m2)
8. No severe liver failure (liver enzymes under twice the upper normal limit)
9. Life expectancy of at least 6 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
32

Key exclusion criteria
1. To not accept to use reliable contraception throughout the study and during three months after cessation of treatment
2. Pregnancy or breast-feeding
3. History of cataracts or increasing risk of cataract formation
4. Severe renal failure (creatinine clearance <30 ml/min/1.73 m2)
5. Active chronic disease such as human immunodeficiency virus (HIV) or hepatitis B or C
6. To have received treatment with iron chelators in the last 6 months
7. Suspected or known hypersensitivity to the drug under study or any of the excipients
8. Dependence or current abuse of drugs or alcohol
9. Treatment with another investigational product in the last 6 months prior to baseline

Date of first enrolment
01/03/2011

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
Spain

Study participating centre
Servicio de Hematología
Zaragoza
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50009

Sponsor information

Organisation
Aragon Institute of Health Sciences [Instituto Aragonés de Ciencias de la Salud] (Spain)

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Sponsor type
Government

Website
http://www.aragon.es/

ROR
https://ror.org/05p0enq35

Funder(s)

Funder type
Government

Funder Name
Aragon Institute of Health Sciences [Instituto Aragonés de Ciencias de la Salud] (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