EU Clinical Trials Register

Help

Home & Search | Joining a trial | Contacts | About

Clinical trials

The European Union Clinical Trials Register allows you to search for protocol and results information on:

- interventional clinical trials that are conducted in the European Union (EU) and the European Economic Area (EEA);
- clinical trials conducted outside the EU / EEA that are linked to European paediatric-medicine development.

Learn more about the EU Clinical Trials Register including the source of the information and the legal basis.

The EU Clinical Trials Register currently displays **24910** clinical trials with a EudraCT protocol, of which **3420** are clinical trials conducted with subjects less than 18 years old.
The register also displays information on **10296** older paediatric trials (in scope of Article 45 of the Paediatric Regulation (EC) No 1901/2006).

Please enter search term... X Search

Examples: Cancer AND drug name. Pneumonia AND sponsor name.
How to search [pdf]

Advanced Search: Search tools

< Back to search results

Summary	
EudraCT Number:	2010-024423-24
Sponsor's Protocol Code Number:	AB10015
National Competent Authority:	Spain - AEMPS
Clinical Trial Type:	EEA CTA
Trial Status:	Ongoing
Date on which this record was first entered in the EudraCT database:	2012-11-29
Trial results	

Index

A. Protocol Information		
A.1	Member State Concerned	Spain - AEMPS
A.2	EudraCT number	2010-024423-24
A.3	Full title of the trial	A prospective, multicenter, randomized, double-blind, placebocontrolled, parallel group, phase 2 study to compare the efficacy and safety of masitinib versus placebo in the treatment of patients suffering from Amyotrophic Lateral Sclerosis (ALS) Estudio prospectivo, Fase II, multicéntrico, randomizado, doble ciego, controlado con placebo, de grupos paralelos para comparar la eficacia y seguridad de masitinib versus placebo en el tratamiento de pacientes con esclerosis lateral amiotrófica (ELA)
A.3.1	Title of the trial for lay people, in easily understood, i.e. non-technical, language	Evaluation of masitinib in Amyotrophic Lateral Sclerosis (ALS) Evaluación de masitinib en Esclerosis Lateral Amiotrófica (ELA)
A.3.2	Name or abbreviated title of the trial where available	not applicable no aplicable
A.4.1	Sponsor's protocol code number	AB10015
A.7	Trial is part of a Paediatric Investigation Plan	No
A.8	EMA Decision number of Paediatric Investigation Plan	

B. Sponsor Information		
B.Sponsor: 1		
B.1.1	Name of Sponsor	ABScience
B.1.3.4	Country	France
B.3.1 and B.3.2	Status of the sponsor	Commercial
B.4 Source(s) of Monetary or Material Support for the clinical trial:		

B.4.1	Name of organisation providing support	ABScience
B.4.2	Country	France
B.5 Contact point designated by the sponsor for further information on the trial		
B.5.1	Name of organisation	ABScience
B.5.2	Functional name of contact point	Alain Moussy
B.5.3	Address:	
B.5.3.1	Street Address	3 avenue George V
B.5.3.2	Town/ city	Paris
B.5.3.3	Post code	75008
B.5.3.4	Country	France
B.5.4	Telephone number	0033147 20 30 08
B.5.5	Fax number	0033147 20 24 11
B.5.6	E-mail	alain.moussy@ab-science.com

D. IMP Identification

D.IMP: 1		
D.1.2 and D.1.3	IMP Role	Test
D.2	Status of the IMP to be used in the clinical trial	
D.2.1	IMP to be used in the trial has a marketing authorisation	No
D.2.5	The IMP has been designated in this indication as an orphan drug in the Community	No
D.2.5.1	Orphan drug designation number	
D.3 Description of the IMP		
D.3.1	Product name	masitinib
D.3.2	Product code	AB1010
D.3.4	Pharmaceutical form	Film-coated tablet
D.3.4.1	Specific paediatric formulation	No
D.3.7	Routes of administration for this IMP	Oral use
D.3.8 to D.3.10 IMP Identification Details (Active Substances)		
D.3.8	INN - Proposed INN	Masitinib mesylate
D.3.9.1	CAS number	790-299-79-5
D.3.9.2	Current sponsor code	AB1010
D.3.9.3	Other descriptive name	na
D.3.10	Strength	
D.3.10.1	Concentration unit	mg milligram(s)
D.3.10.2	Concentration type	equal
D.3.10.3	Concentration number	100
D.3.11 The IMP contains an:		
D.3.11.1	Active substance of chemical origin	Yes
D.3.11.2	Active substance of biological/ biotechnological origin (other than Advanced Therapy IMP (ATIMP)	No
	The IMP is a:	
D.3.11.3	Advanced Therapy IMP (ATIMP)	No
D.3.11.3.1	Somatic cell therapy medicinal product	No
D.3.11.3.2	Gene therapy medical product	No
D.3.11.3.3	Tissue Engineered Product	No
D.3.11.3.4	Combination ATIMP (i.e. one involving a medical device)	No
D.3.11.3.5	Committee on Advanced therapies (CAT) has issued a classification for this product	No
D.3.11.4	Combination product that includes a device, but does not involve an Advanced Therapy	No
D.3.11.5	Radiopharmaceutical medicinal product	No
D.3.11.6	Immunological medicinal product (such as vaccine, allergen, immune serum)	No
D.3.11.7	Plasma derived medicinal product	No
D.3.11.8	Extractive medicinal product	No
D.3.11.9	Recombinant medicinal product	No
D.3.11.10	Medicinal product containing genetically modified organisms	No
D.3.11.11	Herbal medicinal product	No
D.3.11.12	Homeopathic medicinal product	No
D.3.11.13	Another type of medicinal product	No
D.IMP: 2		
D.1.2 and D.1.3	IMP Role	Test
D.2	Status of the IMP to be used in the clinical trial	
D.2.1	IMP to be used in the trial has a marketing authorisation	No
D.2.5	The IMP has been designated in this indication as an orphan drug in the Community	No
D.2.5.1	Orphan drug designation number	
D.3 Description of the IMP		
D.3.1	Product name	masitinib
D.3.2	Product code	AB1010
D.3.4	Pharmaceutical form	Film-coated tablet
D.3.4.1	Specific paediatric formulation	No

D.3.7	Routes of administration for this IMP	Oral use
D.3.8 to D.3.10 IMP Identification Details (Active Substances)		
D.3.8	INN - Proposed INN	Masitinib mesylate
D.3.9.1	CAS number	790299-79-5
D.3.9.2	Current sponsor code	AB1010
D.3.9.3	Other descriptive name	MASITINIB
D.3.9.4	EV Substance Code	SUB32266
D.3.10	Strength	
D.3.10.1	Concentration unit	mg milligram(s)
D.3.10.2	Concentration type	equal
D.3.10.3	Concentration number	200
D.3.11 The IMP contains an:		
D.3.11.1	Active substance of chemical origin	Yes
D.3.11.2	Active substance of biological/ biotechnological origin (other than Advanced Therapy IMP (ATIMP)	No
	The IMP is a:	
D.3.11.3	Advanced Therapy IMP (ATIMP)	No
D.3.11.3.1	Somatic cell therapy medicinal product	No
D.3.11.3.2	Gene therapy medical product	No
D.3.11.3.3	Tissue Engineered Product	No
D.3.11.3.4	Combination ATIMP (i.e. one involving a medical device)	No
D.3.11.3.5	Committee on Advanced therapies (CAT) has issued a classification for this product	No
D.3.11.4	Combination product that includes a device, but does not involve an Advanced Therapy	No
D.3.11.5	Radiopharmaceutical medicinal product	No
D.3.11.6	Immunological medicinal product (such as vaccine, allergen, immune serum)	No
D.3.11.7	Plasma derived medicinal product	No
D.3.11.8	Extractive medicinal product	No
D.3.11.9	Recombinant medicinal product	No
D.3.11.10	Medicinal product containing genetically modified organisms	No
D.3.11.11	Herbal medicinal product	No
D.3.11.12	Homeopathic medicinal product	No
D.3.11.13	Another type of medicinal product	No

D.8 Information on Placebo

D.8 Placebo: 1		
D.8.1	Is a Placebo used in this Trial?	Yes
D.8.3	Pharmaceutical form of the placebo	Film-coated tablet
D.8.4	Route of administration of the placebo	Oral use

E. General Information on the Trial

E.1 Medical condition or disease under investigation

E.1.1	Medical condition(s) being investigated	patients suffering from Amyotrophic Lateral Sclerosis (ALS) Pacientes con esclerosis Lateral Amiotrófica (ELA)
E.1.1.1	Medical condition in easily understood language	Amyotrophic Lateral Sclerosis (ALS) Esclerosis Lateral Amiotrófica
E.1.1.2	Therapeutic area	Diseases [C] - Nervous System Diseases [C10]

MedDRA Classification

E.1.2 Medical condition or disease under investigation

E.1.2	Version	14.1
E.1.2	Level	PT
E.1.2	Classification code	10002026
E.1.2	Term	Amyotrophic lateral sclerosis
E.1.2	System Organ Class	10029205 - Nervous system disorders
E.1.3	Condition being studied is a rare disease	No

E.2 Objective of the trial

E.2.1	Main objective of the trial	The objective is to compare the efficacy and safety of masitinib versus placebo in the treatment of patients suffering from Amyotrophic Lateral Sclerosis (ALS). El objetivo es comparar la eficacia y seguridad de masitinib combinado con riluzol frente a placebo combinado con riluzol en el tratamiento de pacientes con esclerosis lateral amiotrófica (ELA).
E.2.2	Secondary objectives of the trial	Primary endpoint : Amyotrophic Lateral Sclerosis functional rating scale (ALSFRS)-Revised at week 48 Secondary Endpoints: - Amyotrophic Lateral Sclerosis functional rating scale (ALSFRS)-Revised at week 4, 8, 12 and week 36 - Number of failure defined by a 6 point drop in the ALSFRS-R or death - Survival rate at week 12, 24, 36 and week 48 - Overall survival rate - Cystatin C level at week 12, 24, 36, 48

- Forced vital capacity (FVC) score at week 4, 8, 12, 24, 36 and week 48
- Time to first tracheotomy
- ALS SQOLquality of life scale at week 4, 8, 12, 24, 36 and week 48
- Safety: occurrence of Adverse Events (AE), changes on clinical examination including vital signs (blood pressure,
pulse rate) and weight, ECG and laboratory exams (biochemistry, hematology and urinalysis)

Criterios secundarios de valoración:
-Escala revisada de evaluación funcional de la esclerosis lateral amiotrófica (siglas en inglés, ALSFRS) en las semanas 4, 8, 12, 24 y 36.
-Número de fracasos definidos como una disminución de 6 puntos en la escala ALSFRS-R ó fallecimiento desde la visita basal.
-Tasa de supervivencia en las semanas 12, 24, 36 y 48.
-Supervivencia global.
-Nivel de cistatina C en las semanas 12, 24, 36 y 48.
-Puntuación de la capacidad vital forzada (CVF) en las semanas 4, 8, 12, 24, 36 y 48.
-Tiempo transcurrido hasta la primera traqueotomía.
-Cuestionario de calidad de vida específico de la ELA en las semanas 4, 8, 12, 24, 36 y 48.
-Seguridad: aparición de acontecimientos adversos (AA), variaciones en la exploración física incluidas las constantes vitales (presión sanguínea, pulso) y peso, ECG y pruebas analíticas (bioquímica, hematología y análisis de orina).

E.2.3 Trial contains a sub-study: No

E.3 Principal inclusion criteria

INCLUSION CRITERIA:
1. Female or male patient aged between 18 and below 80 and whose weight ≥ 50 kg
2. Familial or sporadic ALS
3. Patient with a verifiable diagnosis of probable or definite ALS
4. Disease duration no longer than 36 months
5. Patient treated with a steady regimen of riluzole (100 mg/day) for a minimum of 1 month before study entry
6. Patient with a FVC (Forced Vital Capacity) ≥ 60%
7. Patient with life expectancy ≥ 6 months
8. Patient with adequate organ function at screening and baseline:
· Absolute Neutrophils Count (ANC) ≥ 2 x 109/L
· Hemoglobin ≥ 10 g/dL
· Platelets (PTL) ≥ 100 x 109/L
· AST/ALT ≤ 2.5 ULN
· Bilirubin ≤ 1.5 ULN
· Albuminemia ≥ 1 x LLN
· Urea ≤ 1.5 x ULN
· Creatinine clearance ≥ 50 mL/min (Cockcroft and Gault formula)
· Proteinuria < 30 mg/dL on dipstick; in case of the proteinuria ≥ 30 mg/dL, 24 hours proteinuria < 1.5g/24 hours
9. Man or woman of child bearing potential, (entering the study after a menstrual period and who have a negative
pregnancy test) who agree to use two methods (one for the patient and one for the partner) of medically acceptable forms of contraception during the study and for three months after the last treatment intake
10. Patient able and willing to comply with study procedures as per protocol
11. Patient able to understand, and willing to sign, and date the written informed consent form at screening visit
prior to any protocol-specific procedures
12. patient able to understand and willing to folow the safety procedures mentioned on the patient card
13. Patient affiliated to a social security system

CRITERIOS DE INCLUSIÓN
1. Pacientes, hombres o mujeres, con edades comprendidas entre 18 y 80 años, con un peso ≥ 50 kg.
2. Pacientes que presenten ELA familiar o esporádica.
3. Pacientes con ELA clínicamente probable o confirmada, diagnosticada de acuerdo con los criterios de El Escorial revisados de la World Federation of Neurology (Brooks, 1994).
4. Pacientes con una duración máxima de la enfermedad de 36 meses desde la aparición de los síntomas, en la visita de selección.
5. Pacientes tratados con una dosis estable de riluzol (100 mg/día) al menos durante los 30 días anteriores a la visita de selección.
6. Pacientes con una CVF (capacidad vital forzada) igual o superior al 60% del valor normal pronóstico para su sexo, estatura y edad en la visita de selección.
7. Pacientes con una esperanza de vida ≥ 6 meses.
8. Pacientes con un funcionamiento orgánico adecuado en la visita de selección y en la visita basal:
? Recuento absoluto de neutrófilos (RAN) ≥ 2 x 10 elevado a 9/l
? Hemoglobina ≥ 10 g/dl
? Plaquetas (PTL) ≥ 100 x 109/l
? AST/ALT ≤ 2,5 x LSN
? Bilirrubina ≤ 1,5 x LSN
? Albuminemia ≥ 1 x LIN
? Urea ≤ 1,5 x LSN
? Aclaramiento de creatinina ≥ 50 ml/min (fórmula de Cockcroft y Gault).
? Proteinuria < 30 mg/dl en tira reactiva; en caso de proteinuria ≥ 30 mg/dl, proteinuria de 24 horas < 1,5 g/24 horas.
9. Hombres o mujeres en edad de procrear, (que participen en el estudio una vez pasado el periodo menstrual y con una prueba de embarazo negativa) deben acceder a utilizar dos métodos anticonceptivos aceptados médicamente (uno para el paciente y el otro para la pareja) durante el estudio y en los tres meses a partir de la última toma del tratamiento.
10. Pacientes capaces y dispuestos a seguir los procedimientos del estudio según el protocolo.
11. Pacientes capaces de entender y dispuestos a firmar y fechar el impreso de consentimiento informado en la visita de selección antes de llevar a cabo cualquier procedimiento específico del protocolo.
12. Pacientes capaces de entender y dispuestos a seguir los procedimientos de seguridad mencionados en la tarjeta del paciente durante los primeros 2 meses de tratamiento.
13. Pacientes afiliados a la Seguridad Social.

E.4 Principal exclusion criteria

EXCLUSION CRITERIA
1. Patient with history of cardiac, hematologic, hepatic, respiratory that is clinically significant for their participation in the study
2. Patient who underwent tracheotomy and /or gastrostomy
3. Patient with a diagnosis of cancer or evidence of continued disease within five years before starting study treatment
4. Patient with significant sensory abnormalities, dementia, other neurologic diseases, uncompensated

medical
illness, substance abuse and psychiatric illness
5. Patient who have participated in a clinical trial within 3 months prior to screening
6. Pregnant, or nursing female patient
7. Patient having cardiac disorders defined by at least one of the following conditions:
· Patient with recent cardiac history (within 6 months) of:
- Acute coronary syndrome
- Acute heart failure (class III or IV of the NYHA classification)
- Significant ventricular arrhythmia (persistent ventricular tachycardia, ventricular fibrillation, resuscitated sudden death)
· Patient with cardiac failure class III or IV of the NYHA classification
· Patient with severe conduction disorders which are not prevented by permanent pacing (atrioventricular block 2 and 3, sino-atrial block)
· Syncope without known aetiology within 3 months
· Uncontrolled severe hypertension, according to the judgment of the investigator, or symptomatic hypertension
8. Patient with history of poor compliance or history of drug/alcohol abuse, or excessive alcohol beverage consumption that would interfere with the ability to comply with the study protocol, or current or past psychiatric disease that might interfere with the ability to comply with the study protocol or give informed consent
PREVIOUS TREATMENTS
9. Patient treated with any investigational agent within 3 months of screening

CRITERIOS DE EXCLUSIÓN
1. Pacientes con antecedentes cardíacos, hematológicos, hepáticos, respiratorios que son clínicamente significativos para su participación en el estudio.
2. Pacientes sometidos a traqueotomía y/o gastrostomía.
3. Pacientes con diagnóstico de neoplasia maligna o indicios de una enfermedad continua en los cinco años anteriores al inicio del tratamiento del estudio.
4. Pacientes con alteraciones sensitivas significativas, demencia, otras enfermedades neurológicas, enfermedad médica descompensada, drogadicción y enfermedades psiquiátricas.
5. Pacientes que han participado en un ensayo clínico en los 3 meses anteriores a la visita de selección.
6. Pacientes embarazadas o en periodo de lactancia.
7. Pacientes con afecciones cardíacas definidas por al menos uno de los siguientes trastornos:
? Pacientes con antecedentes cardíacos recientes (en los 6 meses previos) de:
- Síndrome coronario agudo.
- Insuficiencia cardíaca aguda (clase III o IV según la clasificación de la NYHA).
- Arritmia ventricular importante (taquicardia ventricular persistente, fibrilación ventricular, muerte súbita reanimada).
? Pacientes con insuficiencia cardíaca de clase III o IV según la clasificación de la NYHA.
? Pacientes con trastornos graves de la conducción cardíaca no evitables mediante electroestimulación cardíaca permanente (bloqueo auriculoventricular 2 y 3, bloqueo sinoauricular).
? Síncope sin etiología conocida en los 3 meses previos.
? Hipertensión grave no controlada, a juicio del investigador, o hipertensión sintomática.

8. Pacientes con antecedentes de pobre cumplimiento o drogadicción/alcoholismo, o consumo excesivo de bebidas alcohólicas o enfermedades psiquiátricas presentes o pasadas que pudieran interferir en la capacidad para cumplir el protocolo del estudio o para dar su consentimiento informado.

E.5 End points

E.5.1 Primary end point(s)

Primary endpoints
Amyotrophic Lateral Sclerosis functional rating scale (ALSFRS)-Revised at week 48

Criterio principal
Escala revisada de evaluación funcional de la esclerosis lateral amiotrófica (ALSFRS) en la semana 48.

E.5.1.1 Timepoint(s) of evaluation of this end point

week 48

semana 48

E.5.2 Secondary end point(s)

Secondary endpoints
- Amyotrophic Lateral Sclerosis functional rating scale (ALSFRS)-Revised at week 4, 8, 12, 24 and week 36
- Number of failure deined as 6 drop point in ALSFRS-R or death
- Survival rate at week 12, 24, 36 and week 48
- Overall survival rate
- Cystatin C level from baseline to week 48
- Forced vital capacity (FVC) score at week 4, 8, 12, 24, 36 and week 48
- Time to first tracheotomy
- ALS SQOL quality of life scale at week 4, 8, 12, 24, 36 and week 48
- Safety: occurrence of Adverse Events (AE), changes on clinical examination including vital signs (blood pressure,
pulse rate) and weight, ECG and laboratory exams (biochemistry, hematology and urinalysis)

Criterios secundarios de valoración:
- Escala revisada de evaluación funcional de la esclerosis lateral amiotrófica (siglas en inglés, ALSFRS) en las semanas 4, 8, 12, 24 y 36.
- Número de fracasos definidos como una disminución de 6 puntos en la escala ALSFRS-R ó fallecimiento desde la visita basal.
- Tasa de supervivencia en las semanas 12, 24, 36 y 48.
- Supervivencia global.
- Nivel de cistatina C en las semanas 12, 24, 36 y 48.
- Puntuación de la capacidad vital forzada (CVF) en las semanas 4, 8, 12, 24, 36 y 48.
- Tiempo transcurrido hasta la primera traqueotomía.
- Cuestionario de calidad de vida específico de la ELA en las semanas 4, 8, 12, 24, 36 y 48.
- Seguridad: aparición de acontecimientos adversos (AA), variaciones en la exploración física incluidas las constantes vitales (presión sanguínea, pulso) y peso, ECG y pruebas analíticas (bioquímica, hematología y análisis de orina).

E.5.2.1 Timepoint(s) of evaluation of this end point

week 4, 8, 12, 24, 36

semanas 4, 8, 12, 24, 36

E.6 and E.7 Scope of the trial

E.6 Scope of the trial

E.6.1	Diagnosis	No
E.6.2	Prophylaxis	No

E.6.3	Therapy	Yes
E.6.4	Safety	Yes
E.6.5	Efficacy	Yes
E.6.6	Pharmacokinetic	No
E.6.7	Pharmacodynamic	No
E.6.8	Bioequivalence	No
E.6.9	Dose response	No
E.6.10	Pharmacogenetic	No
E.6.11	Pharmacogenomic	No
E.6.12	Pharmacoeconomic	No
E.6.13	Others	No
E.7	Trial type and phase	
E.7.1	Human pharmacology (Phase I)	No
E.7.1.1	First administration to humans	No
E.7.1.2	Bioequivalence study	No
E.7.1.3	Other	No
E.7.1.3.1	Other trial type description	
E.7.2	Therapeutic exploratory (Phase II)	Yes
E.7.3	Therapeutic confirmatory (Phase III)	No
E.7.4	Therapeutic use (Phase IV)	No
E.8 Design of the trial		
E.8.1	Controlled	Yes
E.8.1.1	Randomised	Yes
E.8.1.2	Open	No
E.8.1.3	Single blind	No
E.8.1.4	Double blind	Yes
E.8.1.5	Parallel group	Yes
E.8.1.6	Cross over	No
E.8.1.7	Other	No
E.8.2	Comparator of controlled trial	
E.8.2.1	Other medicinal product(s)	No
E.8.2.2	Placebo	Yes
E.8.2.3	Other	No
E.8.2.4	Number of treatment arms in the trial	3
E.8.3	The trial involves single site in the Member State concerned	Yes
E.8.4	The trial involves multiple sites in the Member State concerned	No
E.8.5	The trial involves multiple Member States	Yes
E.8.5.1	Number of sites anticipated in the EEA	11
E.8.6 Trial involving sites outside the EEA		
E.8.6.1	Trial being conducted both within and outside the EEA	No
E.8.6.2	Trial being conducted completely outside of the EEA	No
E.8.7	Trial has a data monitoring committee	No
E.8.8	Definition of the end of the trial and justification where it is not the last visit of the last subject undergoing the trial	Study treatment will be discontinued in case of: · Informed consent withdrawal · Adverse or undercurrent event considered intolerable by the patient or incompatible with continuation of the study according to the investigator · Protocol violation (e.g., noncompliance with treatment administration, prohibited treatment needed) El tratamiento en estudio se suspenderá en caso de: - Retirada del consentimiento informado. - Acontecimiento adverso o subyacente considerado intolerable por el paciente o incompatible con su continuidad en el estudio según el investigador. - Violación de protocolo (p.ej., incumplimiento terapéutico, necesidad de seguir un tratamiento prohibido).
E.8.9 Initial estimate of the duration of the trial		
E.8.9.1	In the Member State concerned years	2
E.8.9.1	In the Member State concerned months	0
E.8.9.1	In the Member State concerned days	0
E.8.9.2	In all countries concerned by the trial years	2
E.8.9.2	In all countries concerned by the trial months	0
E.8.9.2	In all countries concerned by the trial days	0

F. Population of Trial Subjects

F.1 Age Range		
F.1.1	Trial has subjects under 18	No
F.1.1.1	In Utero	No
F.1.1.2	Preterm newborn infants (up to gestational age < 37 weeks)	No
F.1.1.3	Newborns (0-27 days)	No
F.1.1.4	Infants and toddlers (28 days-23 months)	No
F.1.1.5	Children (2-11years)	No
F.1.1.6	Adolescents (12-17 years)	No
F.1.2	Adults (18-64 years)	Yes
F.1.2.1	Number of subjects for this age range:	25
F.1.3	Elderly (>=65 years)	Yes

F.1.3.1	Number of subjects for this age range:	17
F.2 Gender		
F.2.1	Female	Yes
F.2.2	Male	Yes
F.3 Group of trial subjects		
F.3.1	Healthy volunteers	No
F.3.2	Patients	Yes
F.3.3	Specific vulnerable populations	Yes
F.3.3.1	Women of childbearing potential not using contraception	No
F.3.3.2	Women of child-bearing potential using contraception	Yes
F.3.3.3	Pregnant women	No
F.3.3.4	Nursing women	No
F.3.3.5	Emergency situation	No
F.3.3.6	Subjects incapable of giving consent personally	No
F.3.3.7	Others	No
F.4 Planned number of subjects to be included		
F.4.1	In the member state	25
F.4.2	For a multinational trial	
F.4.2.1	In the EEA	45
F.4.2.2	In the whole clinical trial	45
F.5	Plans for treatment or care after the subject has ended the participation in the trial (if it is different from the expected normal treatment of that condition)	not different non différent

G. Investigator Networks to be involved in the Trial

N. Review by the Competent Authority or Ethics Committee in the country concerned		
N.	Competent Authority Decision	Authorised
N.	Date of Competent Authority Decision	2013-01-29
N.	Ethics Committee Opinion of the trial application	Favourable
N.	Ethics Committee Opinion: Reason(s) for unfavourable opinion	
N.	Date of Ethics Committee Opinion	2012-12-20

P. End of Trial		
P.	End of Trial Status	Ongoing