A Phase 2a, Randomized, Open-Label Study in Patients with Chronic Hepatitis C Viral Infection to Assess the Safety, Tolerability, Pharmacodynamics, and Antiviral Activity of ANA773 Tosylaat Administered with Ribavirin

Published: 28-04-2011
Last updated: 29-04-2024

- to evaluate the safety and tolerability of oral ANA773 tosylate (ANX8414) administered with ribavirin inpatients with chronic hepatitis C viral (HCV) infection· to evaluate the anti-viral and pharmacodynamic effects of ANA773 tosylate (ANX8414)...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON35795

Source
ToetsingOnline

Brief title
ANA773 with ribavirin in chronic hepatitis C infected subjects

Condition

- Viral infectious disorders

Synonym
hepatitis C; jaundice

Research involving

Human

Sponsors and support

Primary sponsor: Anadys Therapeutics Inc.
Source(s) of monetary or material Support: bedrijven: Anadys Therapeutics Inc. (farmaceutische industrie)

Intervention

Keyword: ANA773, HCV, Hepatitis C

Outcome measures

Primary outcome

Pharmacodynamics:

viral load Hepatitis C.

Safety: adverse events, vital signs, ECG-parameters, laboratory parameters,

physical examination.

Secondary outcome

N/A

Study description

Background summary

Although effectiveness varies for subpopulations, standard-of-care treatment can durably clear HCV infection in only about 50% of treated genotype 1 patients and has significant side-effects that often result in early abandonment of treatment. Thus, there remains a need for new anti-HCV therapies to improve response rates and tolerability.
Immune response plays an important role in controlling and/or possibly clearing chronic
viral Hepatitis infections ANA773 tosylate (ANX8414), an orally administered prodrug of a TLR7 agonist which stimulates
the innate immune response, may therefore offer therapeutic benefit in treating patients with chronic HCV infection, either in combination with standard of care treatments or when combined with direct-acting antiviral agents.

Study objective

- to evaluate the safety and tolerability of oral ANA773 tosylate (ANX8414) administered with ribavirin in
patients with chronic hepatitis C viral (HCV) infection
· to evaluate the anti-viral and pharmacodynamic effects of ANA773 tosylate (ANX8414) administered with
ribavirin in patients with chronic HCV infection.
· to evaluate different dosing schedules of ANA773 tosylate (ANX8414) administered with ribavirin in
patients with chronic HCV infection.

Study design

This will be a randomized, open-label, multiple dose study to evaluate the safety, tolerability, pharmacodynamics,
and antiviral activity of ANA773 administered with ribavirin (ANA773 + ribavirin) following oral administration to
patients with chronic HCV infection.

Intervention

Medication:
- 2000mg ANA773 tosylate for 26 or27 days, combined with ribavirin (bodyweight< 75 kg: 1000 mg and bodyweight>75 kg: 1200 mg);
-Standard of Care therapy: pegylated interferon (180 mcg) with ribavirin.

Study burden and risks

ANA773 tosylate (ANX8414):
flu-like symptoms (fever, chills, myalgia), headache, lymphocytopenia, thrombocytopenia, increased APTT.

Ribavirin:
Aneamia, itchine and rash

Pegays:
fever, chills, rash, itching, painfull or swollen joints, low bloodpressure, increase ALT, neutropenia, thrombocytopenia and (worsening of) depression.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Hepatitis C, genotype 1
IL28B genotypic polymorphism CT
naïve to or have relapsed from prior pegylated interferon-alpha based therapy
Age between 18 - 65 year of each

Exclusion criteria

Pregnant or lactating females;
patient previously treated with experimental drugs for HCV

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	6
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	-
Generic name:	-
Product type:	Medicine
Brand name:	-
Generic name:	ribavirin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Pegasys
Generic name:	pegylated Interferon alpha-2a
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	28-04-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	10-05-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2011-000728-14-NL
CCMO	NL36636.056.11