Immune phenotyping in chronic hepatitis C patients treated with Sofosbuvir and Daclatasvir combination with or without Ribavirin for 12 or 24 weeks -SODA study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27532

Source
Nationaal Trial Register

Brief title
SODA

Health condition

Chronic hepatitis C

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: AMC, BMS

Intervention

Outcome measures

Primary outcome

Immune response:

o Baseline versus end-of-treatment versus follow-up

o Patients with SVR versus patients with non-SVR

o Patients with genotype 1 versus 3 versus 4

Secondary outcome

- SVR12 in the study population

- Proportion of patients with HCV RNA < LLOD at 4 and 24 weeks after cessation of therapy

- Proportion of patients with HCV RNA < LLOD at week 4 during treatment

- Any AE leading to discontinuation of the study drug

Study description

Study objective

- Restoration of HCV-specific T cell function by interferon-free therapy with Sofosbuvir + Daclatasvir ± Ribavirin

- High sustained virological response rates (>90%) in HCV genotype 1, 3 and 4 patients after 12 or 24 weeks combination therapy with Daclatasvir, Sofosbuvir with and without RBV.

- Good tolerability and safety of the combination DCV and SOF with or without RBV.

Study design

Screening, day 0, week 1, 2, 4, 8, 12, 18 and 24 (if applicable) post-treatment week 4, 12, 24

Intervention

Genotype 1 and 4, fibrosis stage F0-F4

Daclatasvir + sofosbuvir

12 weeks

Genotype 3, fibrosis stage F0-F3

Daclatasvir + sofosbuvir + ribavirin

12 weeks

Genotype 3, fibrosis stage F4

Daclatasvir + sofosbuvir + ribavirin

24 weeks

Contacts

Public
Meibergdreef 9
Kamer: G4-214
Meike van der Ree
Amsterdam 1105
The Netherlands
020-5665383
Scientific
Meibergdreef 9
Kamer: G4-214
Meike van der Ree
Amsterdam 1105
The Netherlands
020-5665383

Eligibility criteria

Inclusion criteria

- Subjects infected with HCV genotype 1, 3 or 4.
- Subjects who are treatment-naïve to or relapsed after any previous antiviral therapy other than combination of sofosbuvir + NS5A inhibitor ± ribavirin
- Age: 18 - 65 years
- Males, or post-menopausal or hysterectomized females

Exclusion criteria

- Women of childbearing potential

- Other known cause of liver disease except for CHC

- History or symptoms of decompensated liver disease: Child-Pugh Class B or C, including ascites, hepatic encephalopathy, esophageal variceal bleeding, or other signs of hepatic insufficiency or portal hypertension

- History of hepatocellular carcinoma on imaging studies or serum alpha-fetoprotein (AFP) > 50 ng/mL at screening

- Concurrent clinically significant medical diagnosis

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2014
Enrollment:	32
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-07-2015
Application type:	First submission

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
NTR-new	NL5206
NTR-old	NTR5353
Other	METC/ dossiernummer : 2014_2497/AI444-281

Study results