ISRCTN97560076 https://doi.org/10.1186/ISRCTN97560076

Quality of life in kidney transplant recipients with Hepatitis C Virus (HCV) infection

Submission date
01/08/2018

Recruitment status
No longer recruiting

Registration date
08/08/2018

Overall study status
Completed

Last Edited
11/03/2019

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There is an association between kidney disease and infection with hepatitis C virus (HCV) - sometimes, patients may develop kidney disease as a result of HCV infections; sometimes, they may develop HCV infection through their kidney disease.
Recently, there has been introduction of direct anti-HCV drugs that have radically changed the course of this infection in patients with kidney disease. HCV infection can cause physical and psychological issues for patients. The aim of this study is to determine whether these anti-HCV drugs can improve quality of life for patients with HCV infection after kidney transplantation through eradication of HCV.

Who can participate?
Adult kidney transplant recipients who are infected with HCV and are being treated in the Nephrology and Transplant Unit of the University Federico II of Naples, Italy

What does the study involve?
Participants will be asked to complete 2 questionnaires about quality of life before starting anti-HCV therapy, after its completion (12 weeks after beginning therapy) and 1 year after its completion.

What are the possible benefits and risks of participating?
The benefit to participants taking part in this study is that the anti-HCV treatment will treat the infection and therefore should improve quality of life. The possible risks of participating are the minimal side effects associated with the anti-HCV therapy used, including headaches and gastrointestinal symptoms.

Where is the study run from?
University Federico II, Naples, Italy

When is the study starting and how long is it expected to run for?
October 2015 to February 2018

Who is funding the study?
This study is self-funded

Who is the main contact?
Prof Massimo Sabbatini
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
290/15

Study information

Scientific Title
Eradication of HCV in Renal Transplant Recipients and its effects on Quality of Life

Study objectives
To test the effects of HCV eradication on quality of life (QoL) in renal transplant recipients (RTR)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of “Federico II” University, 26/02/2016, 290/15

Study design
Observational longitudinal case series

Primary study design

Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Hepatitis C Virus in long term renal transplant recipients

Interventions
Participants will be asked to complete 2 different quality of life questionnaires (36-item Short Form Survey (SF36) and Chronic Liver Disease Questionnaire (CLDQ)) at the baseline, at the end of antiviral therapy (12 weeks) and 1 year after its completion. The anti-HCV therapy will be a sofosbuvir-based regimen.

Intervention Type
Other

Primary outcome(s)
Improvements in the different domains (physical and emotional) of quality of life after viral eradication, assessed at the end of HCV antirviral therapy (12 weeks) and 1 year after its completion using the following:
1. 36-item Short Form Survey (SF36)
2. Chronic Liver Disease Questionnaire (CLDQ)

Key secondary outcome(s))
Kidney function, assessed by the stability of calculated glomerular filtration rate (eGFR), calculated using the CKD-EPI creatinine equation at the baseline, at the end of antiviral therapy (12 weeks) and 1 year after its completion.

Completion date
10/02/2018

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Stable eGFR > 30 ml/min
3. Moderate liver stiffness (measured by elastography)
4. Replicating HCV infection

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Total final enrolment
16

Key exclusion criteria
1. Decompensated liver cirrhosis
2. Chronic hepatitis B
3. Human immunodeficiency virus infection
4. Presence of specific intercurrent clinical problems

Date of first enrolment
01/06/2016

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Italy

Study participating centre
University Federico II
Via S. Pansini 5,
Naples
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80131

Sponsor information

Organisation
Comitato Etico "Carlo Romano", Università Federico II di Napoli

ROR
https://ror.org/05290cv24

Funder(s)

Funder type

Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analyses during the current study are available upon reasonable request from Prof. Massimo Sabbatini (sabbatin@unina.it) for the next 12 months, for evaluation of both raw data and of statistical analysis, to discuss together. Patients gave their informed consent to anonymous divulgation of their data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/08/2018	11/03/2019	Yes	No