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Effect of carni Q-gel (ubiquinol and carnitine) on cytokines in patients with heart failure in the TISHCON study

Submission date 14/03/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/03/2007	**Overall study status** Completed	
Last Edited 08/08/2011	**Condition category** Circulatory System	

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
N/A

Study information

Scientific Title

Acronym
The TISHCON Study

Study objectives
Chronic Heart Failure (CHF) represents a major public health burden, and its prognosis is comparable to that of different malignant diseases. CHF progresses because of the activation of neurohormones and pro-inflammatory cytokines, as well as coenzyme Q10 (CoQ) deficiency, following an initial cardiac injury such as Acute Myocardial Infarction (AMI), statin toxicity or a mutation of the genetic programme. It is becoming increasingly apparent that inflammatory mediators play a crucial role in the development of CHF and AMI and several strategies to counterbalance different aspects of the inflammatory response are considered. Possible targets involve pro-and anti-inflammatory cytokines and their receptors, endotoxin, adhesion molecules, nitric oxide and nitric oxide synthase, reactive oxygen species, CoQ and L-carnitine in mitochondria and different types of leucocytes.

The most important cytokines implicated in the progression of CHF are Tumour Necrosis Factor (TNF-alpha), Interleukin (IL)-1, and IL-6. These cytokines share some of their major characteristics (redundancy), and all act in a pro-inflammatory sense. Among those, TNF-alpha is the cytokine that has been studied in greatest detail. IL-10 is anti-inflammatory which is beneficial in heart failure. Cytokines form a vast array of relative low molecular weight, pharmacologically active proteins. These substances are secreted by different cell types for the purpose of altering either their own function (autocrine) or that of adjacent cells (paracrine). Several hypotheses have been suggested to describe the origin of immune activation in CHF. The production of pro-inflammatory cytokines has mostly been attributed to secretion by mononuclear cells, although the myocardium seems to be another important source. Some evidence suggests that catecholamines augment this myocardial cytokine production. There is evidence that CoQ and carnitine may be beneficial in patients with heart failure.

In the present study, we examine, that ubiquinol, in conjunction with L-carnitine, can decrease cytokines and may be useful in patients with CHF.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Reviewed and approved by the Institutional Ethics Committee at Government Medical College, Amritsar, India on the 28th August 2005.

Study design
Double blind, placebo controlled, randomised trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic Heart Failure

Interventions
Nine carni Q-gel softgels (three with each meal thrice daily), which provide a total of 270 mg ubiquinol and 2250 mg L-carnitine daily, or nine matching placebos were administerd to each patient, during the period of 12 weeks. All patients were kept on standard drug therapy, and carni Q-gel and placebo were used as adjuncts to regular drug therapy not as a replacement or substitute.

Laboratory data:
Baseline measurements were taken and repeated after 12 weeks, and a complete blood profile was performed including:
1. Thiobarbituric Acid Reactive Substances (TBARS) and Malondialdehyde (MDA) were obtained by colorimetric methods
2. Resting electrocardiogram and prothrombin time (on anticoagulants) were performed in all the patients at baseline and during follow up whenever indicated
3. CoQ levels in the serum were measured by high pressure liquid chromatography based on an earlier method at Tishcon Corporation (USA)
4. Cytokines Interleukin-six (IL-6), Interleukin-ten (IL-10) and Tumour Necrotising Factors (TNF)-alpha were determined by using a solid phase, two sided chemiluminescence enzyme immunometric assay (immulite automated analyser) kit

The serum samples were kept at -24°C until assay. Results were expressed in pg/ml. The technicians measuring the laboratory data were blind to the groups.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ubiquinol and carnitine

Primary outcome measure
1. Increase in distance walked in six minutes
2. NYHA class of heart failure
3. Echocardiographic cardiac size

Secondary outcome measures

Reduction in TNF-alpha and IL-6

Overall study start date
01/09/2005

Completion date
30/09/2006

Eligibility

Key inclusion criteria
1. Both men and women affected by Chronic Heart Failure (CHF) of mixed etiology
2. Ischaemic, hypertensive, valvular heart disease and idiopathic dilated cardiomyopathy
3. Severity of disease was assessed by New York Heart Association (NYHA) functional Class II to IV

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
62

Key exclusion criteria
1. Hypertrophic cardiomyopathy
2. Amyloid cardiomyopathy
3. Not willing to give consent
4. Patients presenting with shock
5. Chronic renal failure
6. Cancer

Date of first enrolment
01/09/2005

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
India

Study participating centre

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Sponsor information

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Tishcon Corporation (USA)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2007		Yes	No