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Hyaluronic acid and chondroitin sulphate versus placebo in the prevention of urinary infections in female patients with multiple sclerosis.

Submission date
17/03/2015

Recruitment status
No longer recruiting

Registration date
07/04/2015

Overall study status
Completed

Last Edited
26/03/2015

Condition category
Nervous System Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Multiple Sclerosis (MS) is an autoimmune inflammatory disease that causes damage to the myelin sheaths of the nerves in the central nervous system. MS is commonly diagnosed between the ages of 20-40 and is three times more likely to affect women than men. Most (80%) of MS patients report lower urinary tract symptoms (LUTS). The most common is urge incontinence (a sudden need to use the toilet followed immediately by urinating), but MS sufferers also report urinary tract infections(UTIs).UTIs have been associated with relapses and progression of MS. UTIs can made the neurological symptoms in MS worse whilst high-dose steroid treatment of acute neurological worsening may lead to diagnosis of an UTI that had not previously been identified. Half of the women with MS will have at least one episode of UTI requiring antibiotic therapy during their lifetime. Moreover, 25-35% of initial UTI episodes are followed by a recurrent infection within 3-6 months. The chances of someone developing a UTI is complex and depends on genetic, biologic, and behavioural factors. Among the recognised factors, the interaction between the bacteria and the epithelial cells lining the bladder wall is thought to be important. Damage to a layer lining the bladder (the glycosaminoglycan or GAG layer) may expose epithelial cells to urine, which, in turn, may lead to infection. Various approaches have been developed towards a reversal of the damage and a reconstruction of the GAG layer, including the use of heparin, oral pentosan polysulphate, and hyaluronic acid (HA). HA is a major mucopolysaccharide widely found in the connective, epithelial, and neural tissues. Chondroitin sulphate (CS) is also an important structural component for bladder mucosal integrity. Both HA and CS are known to work well in treating cystitis (bladder infection). This suggests that a similar therapeutic approach might be beneficial for treating recurrent UTI. We want to investigate the performance and tolerability of oral administration of combined HA andCS in reducing UTIs and improving the quality of life (QoL) in female patients with multiple sclerosis and a history of recurrent UTIs.

Who can participate?
Women (over 18) with MS that have had at least three UTIs

What does the study involve?
Participants first go to a screening visit to see whether they are eligible. This involves assessment of age, clinical history, symptoms and quality of life. Participants are then randomly allocated into one of two groups. Those in group 1 are given one combined HA and CS capsule twice a day, every day, for 2 weeks and then once a day, every day, for two months. Those in group 2 are given a placebo twice a day, every day, for 2 weeks and then once a day, every day, for two months. UTI assessments are made for all participants before they start the treatment and then after 4,8 and, finally, 12 months.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
The Second University of Naples (SUN) Urology Clinic

When is the study starting and how long is it expected to run for?
May 2015 to May 2016

Who is funding the study?
IBSA (Institut Biochimique SA)

Who is the main contact?
Dr Marco De Sio
marco.desio@unina2.it

Contact information

Type(s)
Scientific

Contact name
Dr Marco De Sio

Contact details
Piazza Miraglia
Napoli
Naples
Italy
80138
00390815665588
marco.desio@unina2.it

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

0000/1

Study information

Scientific Title
Hyaluronic acid and chondroitin sulphate (Ialuril soft gel ® HA 20 mg, CS 200 mg, curcuma longa 200 mg, quercetina 200 mg) versus placebo in the prevention of urinary infections in female patients with multiple sclerosis: a single centre, randomized, placebo-controlled, double-blind trial

Study objectives
The aim of this study is to investigate the efficacy and tolerability of oral administration of combined HA and CS in reducing the rate of UTI and improving the quality of life (QoL) in female patients with multiple sclerosis and a history of recurrent UTIs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Placebo-controlled randomized trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Multiple Sclerosis

Interventions
Eligible patients will receive 1 capsule twice a day of HA and CS (Ialuril soft gel ® HA 20 mg, CS 200 mg, Curcuma longa 200 mg, Quercetina 200 mg), or a placebo every day for two weeks and then once a day for two months.

Intervention Type
Supplement

Primary outcome measure

Mean rate of UTI episodes per patient per year. A UTI episode was defined in the form of significant bacteriuria as >10000 CFU/ml of midstream urine with clinical symptoms.

Assessments measured at baseline and after 4,8 and 12 months.

Secondary outcome measures
1. Time to UTI recurrence (defined as the time relapsed between the first administration and the first recurring infection)
2. Variation in void frequency and volume
3. Impact of therapy on QoL
4. Rate of adverse events

Assessments measured at baseline and after 4,8 and 12 months.

Overall study start date
01/05/2015

Completion date
01/05/2016

Eligibility

Key inclusion criteria
1. Female
2. Age >18years
3. Diagnosis of MS according to the McDonald Revised criteria
4. Expanded Disability Status Scale less < 8
5. Documented history of recurrent cystitis defined as at least three episodes of uncomplicated infection documented by urine culture with the isolation of >10000 CFU/ml of an identified pathogen in the last year with clinical symptoms

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Efficacy data were based both on previously reported data and our own experience in daily clinical practice at our institution. Using type I error and a power of 5% and 80%, respectively, and by proposing the hypothesis that HA would be able to induce a 70% decrease of UTI rate per patient per year, it was calculated that 30 subjects per group were necessary to detect this difference

Key exclusion criteria
1. Age >80 years
2. UTIs in the previous year < 3
3. Concomitant UTI at the beginning of the study or ongoing prophylactic antibiotic treatment
4. Known neoplasia, urinary stone or abnormality of the urinary tract
5. Chronic kidney disease, diabetes mellitus, use of spermicides or intrauterine devices

Date of first enrolment
01/05/2015

Date of final enrolment
01/05/2016

Locations

Countries of recruitment
Italy

Study participating centre
The Second University of Naples (SUN) Urology Clinic (Seconda Università degli studi di Napoli Clinica Urologica)
Piazza Miraglia
Napoli
Naples
Italy
80100

Sponsor information

Organisation
The Second University of Naples (Seconda Università degli studi di Napoli)

Sponsor details
Piazza Miraglia
Napoli
Naples
Italy
80100
0815665588
marcdesio@unina2.it

Sponsor type
University/education

ROR

https://ror.org/02kqnpp86

Funder(s)

Funder type
Industry

Funder Name
IBSA (Institut Biochimique SA)

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available