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Study of sodium hyaluronate injections for trapeziometacarpal osteoarthritis

Submission date
23/01/2012

Recruitment status
No longer recruiting

Registration date
22/02/2012

Overall study status
Completed

Last Edited
14/08/2014

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Hand osteoarthritis (OA) is a common disease, and the trapeziometacarpal joint (TMCJ) is commonly targeted by OA. With respect to the long-term results, Hyaluronic Acid (HA) seems to be the better alternative in the treatment of TMCJ OA, even with a single injection. HA injections were found to be effective in reducing pain and improving fine hand function. The aim of this study was to evaluate the effectiveness of injections of HA for the treatment of pain and disability due to TMCJ OA.

Who can participate?
Patients aged 50 to 80 with symptomatic TMCJ OA treated with Hyaluronic Acid between January 2000 and December 2002.

What does the study involve?
All patients received an injection of Hyaluronic Acid once weekly for three consecutive weeks. Examinations were carried out 1, 3 and 6 months after the first treatment.

What are the possible benefits and risks of participating?
All participants will receive a treatment that may improve pain, radial and palmar abduction, pinch strength, duration of morning stiffness and swelling. There are no known serious risks to participants.

Where is the study run from?
This study has been conducted in the private hospitals Villa Regina, at the rheumatology services , and conducted by Prof. Frizziero as principal investigator.

When is the study starting and how long is it expected to run for?
It is a retrospective study collecting data of patients treated in the period within January 2000 and December 2002.

Who is funding the study?
Hospital Accredited Private Villa Regina [L' Ospedale Privato Accreditato Villa Regina] (Italy).

Who is the main contact?
Dr Nicola Giordan
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Q03-08-01

Study information

Scientific Title
A retrospective study of intra-articular sodium hyaluronate (MW 500-730 KDa) injections for trapeziometacarpal osteoarthritis

Study objectives
The purpose of this retrospective open-label study was to evaluate the efficacy and tolerability of intra-articular injections of HA for the treatment of pain and disability due to trapeziometacarpal joint osteoarthritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Health Authority of Bologna Ethics Committee for Medical Research, 05/05/2009

Study design
Retrospective open-label study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Trapeziometacrpal osteoarthritis

Interventions
All patients underwent one cycle of three weekly intra-articular (i.a.) injections of 0.8 mL (10 mg /mL) of Hyalgan® (hyaluronan) (MW 500 730 KDa) using a dorsolateral approach after palpating the joint space. Joints were injected with a 22-gauge needle after preparation with 10% povidone iodine and ethyl chloride local spray.

Five visits were scheduled:
Visit one: enrolment and start of therapy
Visit two: during study treatment
Visit three: during study treatment
Visit four: during study treatment (1 months after baseline)
Visit five: during study treatment (3 months after baseline)
Visit six: patient final evaluation (6 months after baseline)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
At baseline and at each subsequent observation times at 1, 3 and 6 months after the treatment, the efficacy and safety parameters were assessed by the investigator and by patients. The following variables were considered and recorded during the visits:
1. Anamnestic and demographic data (only at baseline)
2. Spontaneous pain on movement
3. Provoked pain on movement
4. Pain during night and day
5. Morning stiffness
6. Physicians global assessment
7. Patients global assessment
8. Palmar and radial abduction
9. Pinch strength
10. Nonsteroidal Antiinflammatory Drugs (NSAIDs) intake
11. Tolerability of the product

Key secondary outcome(s))
Local or systemic safety profile of Hyalgan®

Completion date
31/12/2002

Eligibility

Key inclusion criteria
1. Patients treated with Hyalgan® in the period within January 2000 and December 2002
2. Patients presenting symptomatic trapeziometacarpal osteoarthritis stated by Kellgren and

Lawrence grade scale
3. Patients with at least 6 months of follow-up
4. Patients aged within 50 and 80 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Arthritic or metabolic pathologies and/or serious trauma
2. Less than 6 months of follow-up
3. Clinically relevant differences in the treatment within enrolled patients

Date of first enrolment
01/01/2000

Date of final enrolment
31/12/2002

Locations

Countries of recruitment
Italy

Study participating centre
Via Rubiani, 2
Bologna
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40124

Sponsor information

Organisation
Hospital Accredited Private Villa Regina [L' Ospedale Privato Accreditato Villa Regina] (Italy)

ROR
https://ror.org/05gwp6g74

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital Accredited Private Villa Regina [L' Ospedale Privato Accreditato Villa Regina] (Italy)

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes