

A POWDER PREPARED FROM SEEDS AND SHELLS OF A SUBTYPE OF ROSA CANINA (LitoZin®) REDUCES PAIN IN PATIENTS WITH OSTEOARTHRITIS OF THE HAND-A DOUBLE-BLIND, PLACEO-CONTROLLED, RANDOMIZED STUDY

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AIM:

To study the impact of a standardised dried powder, LitoZin®, made from hips of a special subtype of *Rosa canina* on:

- Pain and stiffness
- Overall feeling of discomfort
- Consumption of paracetamol

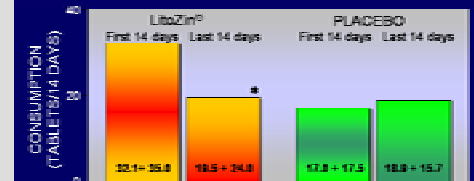
in patients with osteoarthritis of the hand.

We focused on the following fifteen daily activities of the hands and asked the patients: Can you do the following.

- 1) Hold heavy things in your hands?
- 2) Pour from a water jug?
- 3) Hold a cup and use a knife and fork?
- 4) Wring out a dishcloth?
- 5) Peel potatoes?
- 6) Unscrew a bottle top?
- 7) Get the pills out of a blister pack?
- 8) Open a milk carton?
- 9) Tie your shoelaces?
- 10) Manage a toothbrush?
- 11) Write with a pen or pencil?
- 12) Hold a book in your hand for reading?
- 13) Use garden tools?
- 14) Use a corkscrew or a tin-opener?
- 15) Hold or pick up small items from the table?

After each question the patients should comment on their feeling of pain and stiffness

THE MEAN CONSUMPTION OF PARACETAMOL ± SD DURING THE FIRST AND LAST 14 DAYS OF EACH OF THE TWO THREE-MONTH TREATMENT PERIODS (n=13)

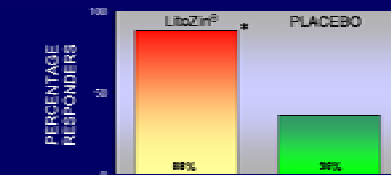


DURING ACTIVE TREATMENT THE CONSUMPTION OF PARACETAMOL TABLETS (500mg) SIGNIFICANTLY DECLINED (*P<0.0322).

METHODS (1):

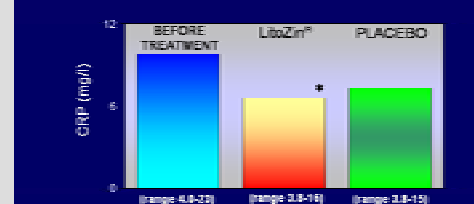
32 patients with osteoarthritis of at least one joint of the hand were randomly allocated to treatment with either LitoZin®, 5 capsules of 0.5 g twice Daily, or identical placebo, for a three-months period, after which they were changed to the alternative treatment.

THE PERCENTAGE OF PATIENTS WHO REPORTED, ON THE YES/NO BASIS, A REDUCTION IN PAIN, AFTER THE INITIAL THREE-MONTH TREATMENT PERIOD.



*P<0.008 vs placebo
APPROXIMATELY ONE OUT OF THREE RESPONDED WITH A REDUCTION IN PAIN TO PLACEBO, WHEREAS APPROXIMATELY NINE OUT OF TEN RESPONDED WITH A REDUCTION IN PAIN IN THE GROUP INITIALLY ACTIVELY TREATED.

C-REACTIVE PROTEIN (CRP) IN PATIENTS BEFORE AND DURING ACTIVE TREATMENT AND PLACEBO (n=8).

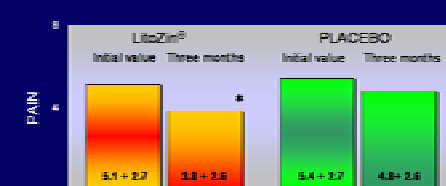


ACTIVE TREATMENT SIGNIFICANTLY LOWERED CRP (P<0.05) AS COMPARED TO PRETREATMENT LEVEL

METHODS (2):

Before and after each of the two treatment periods the patients gave their evaluation of pain and stiffness during 15 different daily activities of the Hands, using a 10 step categorical scale (10=worst possible). Blood was drawn for determination of C-reactive protein at the beginning of the trial and again after the determination of each treatment period. Consumption of rescue medication was recorded in a diary.

PAIN OF THE HAND REPORTED ON A 10-STEP CATEGORICAL SCALE (10=WORST POSSIBLE) DURING HAND WRITING A LETTER.



PAIN SIGNIFICANTLY DECLINED COMPARING THE TWO TREATMENTS (*P<0.0091).

The impact of Active treatment and Placebo on pain (added scores), stiffness (added scores) and overall feeling of discomfort (single question) in patients suffering from osteoarthritis of the hand.

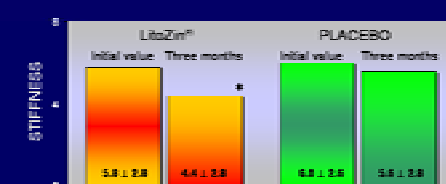
	LitoZin®	Placebo	p value
Pain (mean of 15 scores)	4.8 ± 2.5	5.3 ± 2.6	0.0488
Stiffness (mean of 15 scores)	4.5 ± 2.3	5.1 ± 2.6	0.0571
Overall feeling of discomfort	4.8 ± 2.4	5.5 ± 2.8	0.0324

During Active treatment pain and overall feeling of discomfort from the disease declined as compared to placebo treatment. A similar trend was observed for stiffness.

Flow Chart



STIFFNESS OF THE HAND REPORTED ON A TEN STEP CATEGORICAL SCALE DURING PEELING OF POTATOES



STIFFNESS REPORTED ON A TEN-STEP SCALE (TEN=WORST POSSIBLE) SIGNIFICANTLY DECLINED COMPARING THE TWO TREATMENTS (*P<0.0067).

SIDE EFFECTS

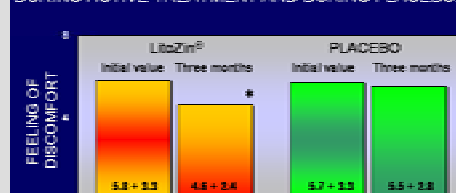
	Placebo	Active treatment
Increased diuresis		1
Transient skin rash		1
Diarrhoea	1	1

No patients dropped out of the study.

DEMOGRAPHICS

32 patients, 28 women and 4 men were included.
Mean age 62 years (range 38 - 92)
Body mass index 24.6 (3.6) kg/m²
All responded positive to a hand grip test
8 patients were on NSAID's
16 patients regularly took Paracetamol
16 patients did not use rescue medication

OVERALL FEELING OF DISCOMFORT, EVALUATED ON A TEN STEP CATEGORICAL SCALE (10=WORST POSSIBLE) DURING ACTIVE TREATMENT AND DURING PLACEBO.



OVERALL FEELING OF DISCOMFORT SIGNIFICANTLY DECLINED COMPARING ACTIVE TREATMENT AND PLACEBO TREATMENT (*P<0.0324).

CONCLUSION:

The present data suggest that LitoZin®

- 1) reduces pain
- 2) reduces stiffness
- 3) improves daily function of the hand
- 4) side effects were comparable to what was observed during placebo