

“Efficacy of Dermoelectroporation treatment on Inflammatory – degenerative pathologies of human locomotive apparatus”

Observation Study carried out at:

S.C. Riabilitazione Ortopedica Ospedale “Eugenio Morelli” di Sondalo **Azienda Ospedaliera della Valtellina e della Valchiavenna**

Project Responsible : Dr. Paolo Buselli

Physical and rehabilitative therapy specialist S.C.-Struttura Complessa RIABILITAZIONE ORTOPEDICA

Primary target of the Observation Study:

Main purpose of this study is to confirm the efficacy of Dermoelectroporation technique whose technical and experimental efficacy has been already proven with previous preliminary clinical investigations.

The experimental evidence of either transdermal delivery and of a high concentration of transdermally delivered substance in the treated area – by using pulsed currents with exponential decay with high peak intensity - indicate Dermoelectroporation as a Therapy able to get to the therapeutic targets in case of local inflammatory syndromes, allowing :

Pharmaceutical substances reduction to be administered,
High efficacy,
General side-effect reduction

Secondary target of the Observation Study:

Secondary purposes are:

To validate Therapeutic protocols,
Evaluate Treatment Frequency and eventual intolerances to the Therapy,
Treatment costs evaluation.

Dermoelectroporation®

- Dermoelectroporation is a Therapy able to transdermally deliver of pharmaceutical substances due to pulsed currents with exponential decay with high peak intensity.
- A previous microdermabrasion treatment is needed to clean the skin up before applying Dermoelectroporation.
- The treatment is carried out by using a vibrating probe and an active substance precision liquid dispenser.

INCLUSION/EXCLUSION CRITERIA

In this study have been included cases of inflammatory pathologies such as [*degenerative, periarthrities*]

1. Enduring radiculopathy [*Spine & Back*]
2. Internal Knees tendinopathy
3. Periarticularis shoulder disease
4. Epicondylitis [*gomito*]

The following patient have been excluded from the study:

1. Allergies problems to the drugs used in this study
2. Osteoporosis
3. Crioglobulinemie
4. Acute infections of either bone and others tissues
5. Pregnancy
6. Bone Cancers
7. Systemic pathologies
8. Patient with Implanted pace-maker
9. Presence of growth cartilages

Ethical aspects & Patient information

The proposed treatment appear to be ethically acceptable because of the following:

- **It is not an invasive treatment,**
- **It requires a limited number of sittings,**
- **It does not have particular risk of unwanted side effects,** in correctly performed,
- **It uses a lower amount of drug Vs the one administer thru other methods** with other therapeutic processes for the same pathology.

All the eligible patients have been previously informed about therapeutic conditions and they are proposed to fill a “consent form”; About the use and information the collection they are asked about a privacy permission document”.

Methods and duration of this Study

1) Clinical scenario definition

1.1 Imaging (diagnosis thru images)

The single patient pathological condition has been determined by means of a Radiographic investigation with specific projections

1.2 Clinical Evaluation

To make a uniform clinical evaluation giving to that a numerical definition, Each single patient's condition will be evaluated thru:

- **VAS scale (Single patient pain evaluation),**
- localized Pain feedback measurement thru Fisher Algometer,

2) Therapeutical Protocol

2.1 Administration

4% 2mg Betametasone phosphate, 2mg Sodium Diclofenac, 1 mg EDTA in a saline solution until 5cc.

2.2 Methods

daily administration for 5 days in a row.

3) Indications to the patient

The patient is informed about the Kinesistherapy exercise to be performed at home.

The proposed Kinesiotherapeutic indications are according to predefined protocols: To this aim a brochure showing what the patient can do and what cannot is suggested.

The Kinesiotherapeutic indications are proposed by a Rehabilitation Therapist right at the first sitting and then verified sitting by sitting

The patient will continue the above exercises for 4 weeks and at the end of this period the patient will be submitted to the first follow-up verification.

4) Other controls

Controls are performed at the end of the therapeutic cycle and after 4 weeks from the therapy conclusion. During the following controls the same methods of the first controls are carried out.

Results

A 50 patient research has been performed. In this research all the assessment and verification as per the protocol has been performed.

The group consists of 33 female and 17 males,
Avg 48,3 years old (DS \pm 14,8 - min 19 y.o.e max 76 y.o.).

The ablove patients have been delivered to this study from either the family doctor or the clinical specialist after traditional clinical approach not giving satisfying results.

Only the following patients have been admitted to the study:

Enduring radicolopathy [*Spine & Back*]
Internal Knees tendinopathy

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Code	Male	Female	Age	vas1	f1	vas2	f2	vas3	f3
B2	1		49	6,5	2,8	5,5	3,2	5,0	3,8
B9	1		76	6,0	2,2	3,0	4,5	3,0	5,5
B8		1	66	7,0	0,5	5,0	2,5	5,0	3,0
B6		1	63	5,0	1,4	5,5	1,4	6,0	1,5
B5	1		39	5,0	1,5	3,0	3,5	4,0	2,5
B4		1	69	8,0	2,0	7,0	2,0	6,0	2,6
B4		1	69	8,0	2,0	7,0	2,0	6,0	2,3
B3	1		56	7,0	0,5	4,0	4,5	3,0	6,0
B1		1	51	6,5	1,8	6,0	2,2	7,0	2,0
BD01		1	54	6,0	2,2	4,0	4,5	2,0	7,0
BG2		1	45	8,0	2,5	3,0	6,0	2,0	7,0
BG1		1	45	9,0	2,0	6,0	2,6	5,0	2,8
BG6	1		37	6,0	3,0	3,0	7,5	3,0	7,0
BG3		1	44	7,0	1,8	5,0	2,6	4,0	3,0
BG4	1		38	6,0	2,2	3,0	4,5	2,0	6,0
BG5		1	63	6,0	1,4	2,0	3,5	1,0	5,0
BG11		1	41	6,0	2,5	4,0	4,5	4,0	5,0
BG10		1	46	6,0	1,8	4,0	2,7	4,5	2,6
BG12		1	38	8,0	2,0	5,0	6,0	2,0	7,0
BG14	1		34	6,0	2,5	3,0	8,0	2,0	7,0
BF1	1		19	6,0	2,0	4,5	2,6	3,0	3,5
BUOT10	1		40	8,0	1,8	3,0	3,0	4,0	2,0
BUAG1	1		60	9,0	1,8	4,0	2,5	3,0	3,5
BLU7		1	54	7,0	1,5	5,0	2,8	4,0	2,0
BLU6		1	69	8,0	1,2	5,0	1,9	4,0	3,5
BLU5		1	28	8,0	1,4	5,0	2,5	3,0	3,6
BGIU10		1	63	6,0	1,6	2,0	3,5	1,0	4,0
BGIU8		1	54	7,0	1,6	4,0	2,3	2,0	3,2
BLU9	1		42	6,0	2,5	4,0	2,6	5,0	2,3
BGIU5	1		25	8,0	1,5	7,0	1,6	7,0	1,5
BGIU1		1	63	9,0	1,3	5,0	2,1	3,0	2,4
BMA11		1	64	7,0	1,7	5,0	2,0	4,0	2,3
BMA12	1		72	8,0	1,4	3,0	2,5	2,0	3,2
BMA6	1		31	6,0	2,5	1,0	5,0	1,0	5,2
BMA7	1		60	6,0	2,2	6,0	2,3	7,0	1,9
BGIU9		1	48	8,0	2,3	6,0	2,2	5,0	2,6
BMA13		1	27	8,0	1,4	4,0	3,5	3,0	3,8
BMA2		1	49	9,0	1,6	6,0	2,5	5,0	3,0
BMA3		1	47	9,0	1,0	8,0	1,2	7,5	1,4
BMA8		1	40	8,0	1,4	4,0	2,8	3,0	3,5
BA3		1	27	7,0	1,8	4,0	2,5	2,0	3,2
BA2		1	43	7,0	1,6	4,0	3,0	3,0	3,5
BM7		1	71	7,0	1,5	3,0	3,0	2,0	3,5
BM2		1	35	6,0	1,2	4,0	2,2	2,0	3,4
BF9		1	63	6,0	1,2	4,0	2,2	3,0	2,9
BF8		1	63	7,0	1,6	4,0	2,5	3,0	3,0
BF10		1	25	8,0	1,0	6,0	1,4	7,0	1,5
BF6		1	27	8,0	0,8	6,0	1,4	6,0	1,5
BF4	1		43	8,0	2,2	7,0	3,2	7,0	2,4
BF5	1		39	7,0	1,5	7,0	1,2	7,0	1,4
TOTALE	17	33							
MEDIA			48,3	7,10	1,73	4,57	3,04	3,90	3,47
Dev.St.			14,8	1,09	0,54	1,51	1,48	1,85	1,64

Legend

Code per patient

vas1 Numerical index for V.A.S.

f1 Numerical index for Fisher Algometer

vas2 Numerical index for V.A.S. Therapeutic cycle conclusive control

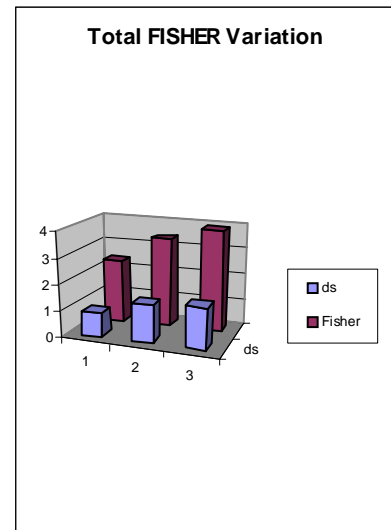
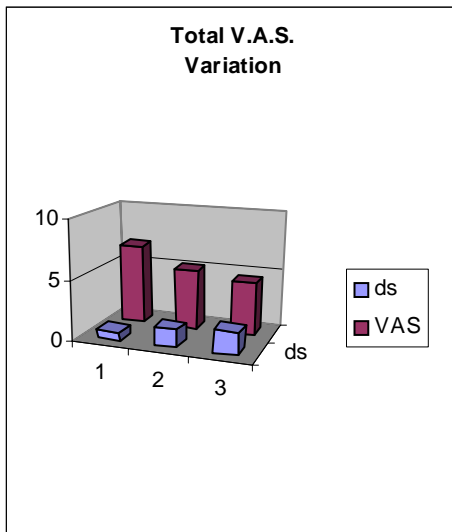
f2 Numerical index for Fisher Algometer Therapeutic cycle conclusive control

vas3 Numerical index for V.A.S. 4 weeks after Therapeutic cycle conclusion

f3 Numerical index for Fisher Algometer 4 weeks after Therapeutic cycle conclusion

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Graphic trend through either V.A.S. and Fisher algometer scale



The shown results demonstrate a positive response from the whole treated patient group for:

- V.A.S. Scale feedback
- Fisher Algometer on painful points feedback

[Research duration : 18 months followed , since the outstanding outcome, by a continuative application routine]

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Conclusions

•Since the outstanding result we got and from the bibliography acquired, this clinical dept has been using this methods to solve those pathologies that we think they be eligible for Transdermal delivery.

•Further treated cases are normally inserted into the therapeutic routine of this dept. Without need of being validated from an observational evaluation.

•The number of patients treated is about several hundreds with great results especially if compared to the ones obtainable from other physical therapies.

Suggestions

Goal of further improving will be transdermal delivery of active substances by means of an electromagnetic syringe allowing the user to deliver various pharmaceutical substance right in the areas needing to be treated and even in case of local deep areas. This will be realized with no waste of drug that may go all around the body but not right there where it needed.

We think it might be interesting to enlarge this study to other specific pathologies such as Tendis retraction, penis plastic hypertrophy.



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