

The effect of Normast (PEA) on neuropathic pain in Spinal Cord Injury

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Introduction:

Neuropathic pain after spinal cord injury (SCI) is a significant, unresolved problem causing suffering and reduced quality of life in patients with SCI.

Treatment of neuropathic pain is complex and many patients have incomplete relief from present available and recommended treatment.

Palmitoylethanolamide (PEA) is a fatty acid which is produced in the body. It potentiates the body's own cannabis-like substances (endocannabinoids) and reduces pain and inflammation.

Clinical trials support the use of PEA on neuropathic pain. So far no studies have been published in patients with SCI.

Normast is a medical supplement, approved for us in Denmark, which contains PEA.

Aims:

To investigate the effect of Normast (PEA), on neuropathic pain in patients with spinal cord injury.

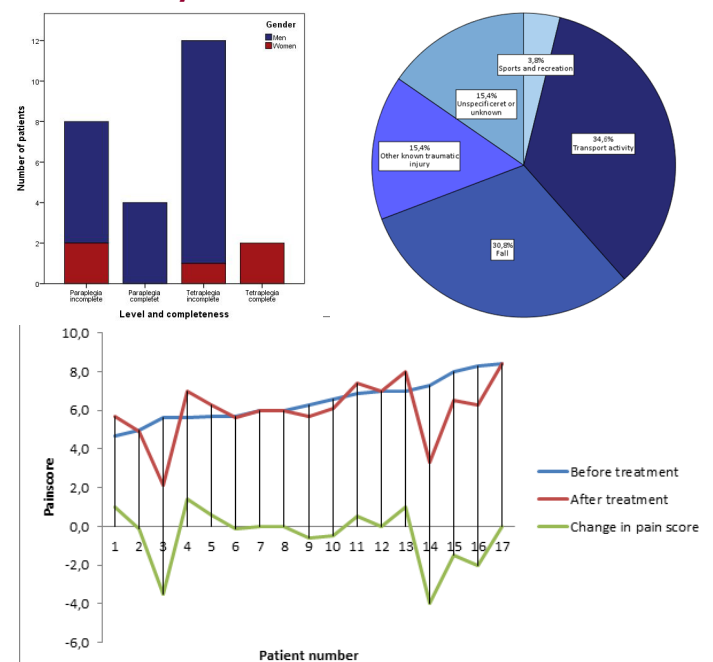
Population characteristics:

Gender	
Female (N)	5
Male (N)	21
Level and completeness	
Tetraplegia complete (N)	2
Tetraplegia incomplete (N)	4
Paraplegia complete (N)	12
Paraplegia incomplete (N)	8
Age at time of inclusion, years (mean \pm SD)	56.4 (\pm 9.5)
Time since injury, years (mean \pm SD)	8.4 (\pm 8.9)

Methods:

A randomized, double-blind, placebo-controlled parallel study. 66 patients with neuropathic pain due to SCI will be included. Multiple questionnaires regarding neuropathic pain, spasticity, insomnia, anxiety and depression are completed before and after treatment with either placebo or Normast. A numeric rating scale for pain intensity (0-10 point) is used to measure primary outcome.

Preliminary results:



Present status:

40 patients are included of which 24 have completed the trial. No major side effects have been reported and no drop-outs so far. Some patients have reported positive effect on neuropathic pain which they ascribe as an effect of Normast.

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