Acupuncture in acute herpes zoster pain therapy (ACUZoster) - design and protocol of a randomised controlled trial.

BACKGROUND: Acute herpes zoster is a prevalent condition. One of its major symptoms is pain, which can highly influence patient's quality of life. Pain therapy is limited. Acupuncture is supposed to soften neuropathic pain conditions and might therefore act as a therapeutic alternative. Objective of the present study is to investigate whether a 4 week semi-standardised acupuncture is non-inferior to sham laser acupuncture and the anticonvulsive drug gabapentine in the treatment of pain associated with herpes zoster. METHODS/DESIGN: Three-armed, randomised, placebo-controlled trial with a total follow-up time of 6 months. Up to estimated 336 patients (interim analyses) with acute herpes zoster pain (VAS> 30 mm) will be randomised to one of three groups (a) semi-standardised acupuncture (168 patients); (b) gabapentine with individualised dosage between 900-3600 mg/d (84 patients); (c) sham laser acupuncture. Intervention takes place over 4 weeks, all patients will receive analgesic therapy (non-opioid analgesics: metamizol or paracetamol and opioids: tramadol or morphine). Therapy phase includes 4 weeks in which group (a) and (c) consist of 12 sessions per patient, (b) visits depend on patients needs. Main outcome measure is to assess the alteration of pain intensity before and 1 week after...
treatment sessions (visual analogue scale VAS 0-100 mm). Secondary outcome measure are: alteration of pain intensity and frequency of pain attacks; alteration of different aspects of pain evaluated by standardised pain questionnaires (NPI, PDI, SES); effects on quality of life (SF 36); analgesic demand; alteration of sensoric perception by systematic quantitative sensory testing (QST); incidence of postherpetic neuralgia; side effects and cost effectiveness. Credibility of treatments will be assessed. DISCUSSION: This study is the first large-scale randomised placebo controlled trial to evaluate the efficacy of acupuncture compared to gabapentine and sham treatment and will provide valuable new information about the clinical and physiological effects of acupuncture and gabapentine in the treatment of acute herpes zoster pain. The study has been pragmatically designed to ensure that the study findings can be implemented into clinical practice if acupuncture can be shown to be an effective treatment strategy in acute herpes zoster pain. TRIAL REGISTRATION: NCT00885586.