Trial Description

Title

The quality of spontaneus movements in preterm infants undergoing craniosacral therapy

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Within the last years several animal and human studies showed that tactile/kinaesthetic stimulation were associated with promising results, suggesting positive influence on weight gain, motor - and neurodevelopmental outcome in infants. As very low birth weight infants are extremely small and delicate to touch, we considered craniosacral therapy as ideal form of soft kinaesthetic stimulation in healthy prterm infants.
Included are stable preterm infants (GA < 37 weeks), without neurological pathologies in the ultrasound examination.The infants were randomized either into the intervention group (IG) who received craniosacral therapy, or the control group (CG).
The Intervention group receive craniosacral therapy for 3 weeks , each session for 20 minutes, twice a week.
By videodocumentation the General Movement (GM) assessment before and after the intervention were documented. To blinded experts analyses GM Optimality Score (0-42 points). Higher scores indicate a more optimal performance.

Brief Summary in Scientific Language

Tactile/kinaesthetic stimulation includes a variety of different techniques, craniosacral therapy being one of it. As very low birth weight infants are extremely small and delicate to touch, we considered (a) craniosacral therapy as ideal form of additional enrichment of the environment by soft kinaesthetic stimulation and (b) the non intrusive GM assessment as the appropriate tool to evaluate its implications. The aims of our study were (1) to investigate neurological short-term effects of craniosacral therapy and (2) to evaluate a difference in weight gain in relation to the therapeutical approach of craniosacral therapy

Do you plan to share individual participant data with other researchers?

[---]*

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[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00004258**
- Date of Registration in DRKS: **2012/07/31**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **IRB00002556 , Ethikkommission der Medizinischen Universität Graz**

Secondary IDs

Health condition or Problem studied

- Free text: **Preterm**
- ICD10: **P07.3 - Other preterm infants**

Interventions/Observational Groups

- Arm 1: <style fontName='DejaVu Sans' isBold='true'>Preterms (GA<37 Weeks) undergoing craniosacraltherapy for 3 weeks, each intervention for 20 minutes-twice a week</style>
- Arm 2: <style fontName='DejaVu Sans' isBold='true'>Preterms (GA<37 Weeks) without craniosacraltherapy</style>

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

- Blinding: **[---]***
- Who is blinded: **investigator/therapist, assessor**
- Control: **Control group receives no treatment**
- Purpose: **Supportive care**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

**Quality of the General Movements in preterms undergoing craniosacraltherapy
Scoring: General Motor Optimaltity Score
measured-15 min before and after the Intervention**

Secondary Outcome

Weight differencs in preterms undergoing craniosacral therapy-before the first and after the last intervention

Countries of recruitment

- AT **Austria**

Locations of Recruitment

- Medical Center **Abteilung für Neonatologie, Graz**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/08/01**
- Target Sample Size: **30**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **24 Weeks of pregnancy**
- Maximum Age: **37 Weeks of pregnancy**

Additional Inclusion Criteria

clinical "stable" preterms

Exclusion criteria

Preterms with cerebral diagnosis

Addresses

- **Primary Sponsor**

  Abteilung für Neonatologie
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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/10/25**

Trial Publications, Results and other documents

- Trial results **BMC Complementary and Alternative Medicine.2016, 16:12**

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*