SÄPT

Schweizerische Aerztegesellschaft für Psycholytische Therapie
(Swiss Medical Society for Psycholytic Therapy)

LSD-assisted psychotherapy in persons suffering from anxiety symptoms in severe somatic diseases or in psychiatric anxiety disorders: a double-blind, randomized, and placebo-controlled phase-II-study

Concept

From 2008 until 2012, a pilot study in LSD-assisted psychotherapy was conducted to evaluate efficacy and safety of this method in persons suffering from anxiety in life-threatening diseases. This study showed promising results (see literature at the end of this information). After this successfully finished pilot study a confirmatory study is now planned with a greater number of participants to show statistically more robust results. As a phase II study the project could be considered one of the necessary steps to take for making LSD a licensed medication again.

Since the course of anxiety symptoms during the treatment was the main systematic observation (Spielberger State and Trait Anxiety Inventory, STAI) in the pilot study, we want to follow also this concept in the second study. But beside patients suffering from anxiety in life threatening diseases (e.g. cancer) we plan to include other patients with anxiety problems (e.g. generalized anxiety disorder) as well to gain information about the efficacy of the treatment in other specified anxiety problems.

The trial uses a double-blind randomized and balanced crossover-design with two identical psychotherapy treatment phases of four to five months during which two full day LSD- or Placebo-sessions six to ten weeks apart take place.

Over a period of about 4 years (if a follow-up is investigation after 24 months is included, it will take one year more) approximately 40 participants shall be included in the study, so that we have at least 30 complete data sets for statistical evaluation. The primary study endpoint is reduction of anxiety (STAI) after 6 months of treatment by LSD compared with placebo (within-subjects, N=30). Based on the results of the pilot study we expect valid results with sufficient statistical power. Furthermore the study design allows a between subject analysis of the effects of LSD shown by the changes in STAI compared to placebo for the first 6 months of treatment (N=15 per group) and a within-subject comparison for all subjects completing the full 12-month study period. Secondary study endpoints are reductions in depression (Hamilton Depression Scale, HAMD) and general psychopathological symptoms (Symptom Check List 90 items, SCL-90). The acute effects of LSD and placebo will be assessed using the Altered States of Consciousness Questionnaire (ASC) and freely written self-reports. A possible relationship between the acute LSD effects in the ASC scale and the potential long-lasting therapeutic effects will be investigated as well.

Conducting of the study

The University Hospital Basel acts as the legal sponsor and investigator of the study (Prof. Dr. Matthias Liechti) and manages the production of the study medication, regulatory affairs, GCP (Good Clinical Practice) compliance, quality control, data management and publication.

Screening, (interviews, inclusion / exclusion, physical and laboratory examination) as well as the treatment takes place in the private practice of the psychiatrist Dr. Peter Gasser (supported by study personnel). Thus, an experienced team will guarantee for the scientific integrity and compliance with GCP and the local regulatory requirements for this study. The start of the study is planned for May 2017.

Time and events schedule

Time in weeks		0		4		10		12		26		30		36		38		52		104
	Screening	Start		LSD/Placebo day 1		LSD/Placebo day 2		End of treatment phase		Outcome assess-ment /crossover		Placebo/LSD day 1		Placebo/LSD day 2		End of treatment phase		outcome assess-ment		12-month follow-up
Interview	x																			
Physical Exam	x																	x		
Psychotherapy sessions			x		x		x				x		x		x					
Measurements (STAI, HAMD; SCL-90)		x		x		x		x		x		x		x		x		x		x
Acute effect measurements (ASC, self reports)				x		x						x		x						

Budget

Costs

- **Administration, data analysis, publication** CHF 200‘000.-
  Writing study protocol, regulatory approval and reporting, study monitoring, data analysis, and publication
- **Production of the medicinal products (LSD/placebo)** CHF 50‘000.-
  Purchase, capsulation (GMP documentation), randomization, periodical quality tests
- **Screening and therapy costs** for 40 participants CHF 200'000.-
  160 full day LSD sessions (8hours CHF 125 per hour),
  400 talking psychotherapy sessions (CHF 150 per hour),
  administration of treatment and research

Total study expenses **CHF 450‘000.-**

Earnings

The costs of the study partly will be covered by the University Hospital Basel through using of their infrastructure like scientific database, insurance covering etc. Sponsoring by the pharmaceutical industry or official grants is not probable.

Thus the study mainly will be financed through private sponsoring. The Swiss Medical Society for Psycholytic Therapy (SAePT) will formally act as the official main sponsor of the study. Vanja Palmers, Lucerne (vanjapalmers@icloud.com) agreed to act as fundraiser.

Information for sponsors / Procedure of Sponsoring and control over the money from donations

All donations are proceeded to a study account of the **Schweizerische Aerztegesellschaft fuer Psycholytische Therapie (SAePT), 4500 Solothurn, IBAN (international bank account number) CH78 0900 0000 8971 4631 0**. According to Swiss law SAePT is exempt from taxes so that donations for the study are tax deductible.

The control over the donations and their right use is made on three levels. First, the study account is part of the SAePT accountancy and therefore periodically controlled by the accountancy revision of the association. Second, the General assembly of SAePT has to accept the annual report of the accountancy. And third we have to submit the annual general report and the accountancy report of the association to the tax administration.

Literature

1. Gasser P, Holstein D, Michel Y, Doblin R, Yazar-Klosinski B, Passie T, Brenneisen R.
Safety and efficacy of lysergic acid diethylamide-assisted psychotherapy for anxiety associated with life-threatening diseases.
Nerv Ment Dis. 2014 Jul;202(7):513-20. doi: 10.1097/NMD.0000000000000113.

2. Gasser P, Kirchner K, Passie T
LSD-assisted psychotherapy for anxiety associated with a life-threatening disease: A qualitative study of acute and sustained subjective effects
J Psychopharmacol January 2015 29: 57-68, first published on November 11, 2014 doi:10.1177/0269881114555249

Full text of these papers and more literature on demand

Contact

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