KURZPROTOKOLL
EARLY

Öffentlicher Titel	Frühzeitige Gabe von Clozapin bei akuter Schizophrenie
Wissenschaftl. Titel	Effects of early clozapine treatment on remission rates in acute schizophrenia (EARLY)
Kurztitel	EARLY
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, doppelblind, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Psyche: Schizophrenie
Einschlusskriterien	- Age 18 to 65 years - Signed informed consent - DSM-V diagnosis of schizophrenia confirmed by the Mini international Neuropsychiatric Interview - At least one documented prior hospitalization due to the illness in the medical history (the current hospitalization can be considered as “prior” hospitalization if its 4 weeks) at screening - For treatment-naïve patients (defined as no previous antipsychotic treatment or a maximum of 30 days of treatment), an antipsychotic treatment attempt of at least 30 days with an antipsychotic in a therapeutic dose according to local guidelines other than clozapine and olanzapine before the screening phase is needed. For non-treatment-naïve patients (defined as having been treated for more than 30 days with an antipsychotic), a discontinuation of a foregoing antipsychotic treatment prior to the screening phase within a maximum of six months (=180 days) is possible (corresponding to the estimated average time for an antipsychotic washout phase and the expected time to develop a relapse of the disease). For patients being treated with a long-acting antipsychotic (other than PP3M), an inclusion is possible if inclusion date corresponds to the planned date of the next injection plus five to seven days - Clinical need for a medication switch because of clinical inefficacy or side-effects or clinical need for a reintroduction of an antipsychotic treatment after treatment discontinuation prior to the screening phase (see 5.) - Moderate symptomatology on the PANSS, defined as a score >= 4 for two or more symptoms from P1-P7 or a score of 6 for one symptom from P1-P7 (minimum threshold definition) at screening - Male participants and female participants who are not capable of bearing children or who use a method of contraception that is medically approved by the health authority of the respective country at screening: a) A woman who is not capable of bearing a child is defined as follows: post-menopausal (12 months natural (spontaneous) amenorrhea or 6 months spontaneous amenorrhea with serum-FSH-values (follicle-stimulating hormone) of >40 mIU/mL); 6 weeks after a bilateral ovariectomy with or without hysterectomy or sterilization by means of tubal ligation b) A woman capable of bearing child is defined as follows: a woman who is physiologically capable of becoming pregnant, including women whose occupation, lifestyle or sexual orientation exclude sexual intercourse with a male partner and women whose partners have been sterilized by vasectomy or other measures. c) Medically-approved methods of contraception can include the following: hormonal contraceptives, intrauterine device and double barrier method. Acceptable preventive measures can include total abstinence at the discretion of the investigator, in cases where compliance is ensured because of the study participant’s age, occupation, lifestyle or sexual orientation. Periodical abstinence (e.g. calendar, ovulation, symptothermal methods or abstinence until the 4th day after the ovulation) as well as coitus interruptus are not acceptable methods of contraception. d) A reliable method of contraception (CTFG guideline) must be used for the entire duration of the study.
Ausschlusskriterien	- Patients who are not suitable for the study in the opinion of the investigator

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	- Patients who are unable to give informed consent - Coercive treatment at the time of study inclusion - White blood cell count (WBC) at inclusion not meeting the requirements for clozapine use in Germany. Patients must have normal leukocyte findings (white blood cell count >= 3500/mm3 (>= 3.5x109/l), and Absolute Neutrophil Count (ANC) >= 2000/mm3 (>= 2.0x109/l) at the screening visit - The presence of one or more of the contraindications against any of the study drugs as mentioned in the SPC - Treatment-naïve or treatment-resistant schizophrenia. Treatment-naïve will be defined as no previous antipsychotic treatment or a maximum of 30 days of treatment. Treatment resistance is defined as 2 antipsychotic trials (with antipsychotics from two different chemical classes) for a period of 6 weeks with CPZ equivalent doses 600 mg/day, both of which took place immediately before the screening phase - Diagnosis of primary substance dependency other than nicotine - Documented previous non-response to an 8-week drug trial with olanzapine or previous treatment with clozapine - Intolerance to one of the study drugs - Pregnancy (incl. positive urine pregnancy test) / lactation (female patients)
Alter	18 - 65 Jahre
Prüfzentren	**Psychiatrie, Psychosomatik und Psychotherapie** (Geschlossen) Heinrich-Hoffmann-Straße 10 60528 Frankfurt am Main Dr. med. David Prvulovic
Sponsor	Universitätsklinikum München
Förderer	Deutsche Forschungsgemeinschaft
Registrierung in anderen Studienregistern	EudraCT 2018-001514-15 Deutsches Register Klinischer Studien DRKS00016043 (primäres Register)

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