Clinical trial results:
TAILOR - a randomized clinical trial: Tapered discontinuation versus maintenance therapy of antipsychotic medication in patients with newly diagnosed schizophrenia or schizophreniform psychosis in remission of psychotic symptoms

Summary

EudraCT number	2016-000565-23
Trial protocol	DK
Global end of trial date	19 October 2020

Results information

Result version number	v1 (current)
This version publication date	28 May 2021
First version publication date	28 May 2021

Trial information

Trial identification

Sponsor protocol code	2016-867

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Copenhagen Research Center for Mental Health, CORE
Sponsor organisation address	Gentoftehospitalsvej 15, 4. sal, Hellerup, Denmark, 2900
Public contact	Merete Nordentoft, Copenhagen Research Center for Mental Health, CORE, Merete.Nordentoft@regionh.dk
Scientific contact	Merete Nordentoft, Copenhagen Research Center for Mental Health, CORE, Merete.Nordentoft@regionh.dk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 December 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 October 2020
Global end of trial reached?	Yes
Global end of trial date	19 October 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

1. To investigate the frequency of subjects who are not in treatment with antipsychotic medication and has remission of psychotic symptoms in the discontinuation group compared with the maintenance therapy group measured at one and two year follow up.

Protection of trial subjects:

Safety was ensured by regular visits in the early intervention service, monthly telephonic assessment of psychotic symptoms and monitoring by Good Clinical Practice (GCP) including reports of adverse events/reactions and serious adverse events/reactions.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 May 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 29
Worldwide total number of subjects	29
EEA total number of subjects	29

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	29
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Evaluated by medical doctors

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind[1]
Roles blinded	Data analyst, Assessor[2]

Arms

Are arms mutually exclusive?	Yes
Arm title	intervention

Arm description:

Patients within this arm received tapered discontinuation of their antipsychotic medication

Arm type	Tapered discontinuation
Investigational medicinal product name	Any antipsychotic medication approved for schizophrenia or schizophreniform psychosis
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection, Oral drops, Tablet
Routes of administration	Intramuscular use, Oral use

Dosage and administration details:

Study participants were tapered off their antipsychotic medication which they already took before entering the trial

Arm title	control

Arm description:

Study participant received usual maintenance treatment with antipsychotic medication

Arm type	No intervention

No investigational medicinal product assigned in this arm

Notes:

[1] - The number of roles blinded appears inconsistent with a single blinded trial. It is expected that there will be one role blinded in a single blind trial.

Justification: assessors and researchers were blinded to the randomization. But neither study participant nor clinicians were blinded.

[2] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: assessors and researchers were blinded to the randomization. But neither study participant nor clinicians were blinded.

Number of subjects in period 1	intervention	control
Started	14	15
Completed	11	12
Not completed	3	3
Consent withdrawn by subject	1	-
Protocol deviation	2	3

Baseline characteristics

Reporting groups	
Reporting group title	intervention
Reporting group description:	
Patients within this arm received tapered discontinuation of their antipsychotic medication	
Reporting group title	control
Reporting group description:	
Study participant received usual maintenance treatment with antipsychotic medication	

Reporting group values	intervention	control	Total
Number of subjects	14	15	29
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	14	15	29
From 65-84 years	0	0	0
85 years and over	0	0	0
not recorded	0	0	0
Gender categorical Units: Subjects			
Female	9	8	17
Male	5	7	12
not recorded	0	0	0

End points

End points reporting groups

Reporting group title	intervention
Reporting group description:	
Patients within this arm received tapered discontinuation of their antipsychotic medication	
Reporting group title	control
Reporting group description:	
Study participant received usual maintenance treatment with antipsychotic medication	

Primary: Remission of psychotic symptoms (meaning SAPS ≤ 2) in minimum three months and no antipsychotic medication in minimum three months

End point title	Remission of psychotic symptoms (meaning SAPS ≤ 2) in minimum three months and no antipsychotic medication in minimum three months[1]
End point description:	
End point type	Primary
End point timeframe:	
7th of May 2018 to 1st of June 2020	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses were made due to an insufficient number of included participants and analysis made would potentially be misleading

End point values	intervention	control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	13		
Units: participants	5	2		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 3rd of July to 6th of January 2020	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	10.0
Reporting groups	
Reporting group title	intervention
Reporting group description: -	
Reporting group title	control
Reporting group description: -	

Serious adverse events	intervention	control	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 14 (14.29%)	3 / 15 (20.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Psychiatric disorders			
Hospitalisation			
subjects affected / exposed	1 / 14 (7.14%)	2 / 15 (13.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	1 / 14 (7.14%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy			
subjects affected / exposed	0 / 14 (0.00%)	1 / 15 (6.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	intervention	control	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 14 (7.14%)	2 / 15 (13.33%)	
Social circumstances			
Substance use	Additional description: contact with police		
subjects affected / exposed	0 / 14 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Treatment noncompliance			
subjects affected / exposed	0 / 14 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Psychiatric disorders			
Psychotic behaviour			
subjects affected / exposed	1 / 14 (7.14%)	0 / 15 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 March 2018	Change of inclusion criteria from patients having received 11 months treatment in an OPUS team to having 12 months left of treatment
08 March 2019	The use of a mobile phone application was discarded, adjustment of expected number of included study participants, inclusion of one more trial site and deletion of five-year follow-up.
22 July 2020	Deletion of two-year follow-up

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported