RAND SCEPC Anti-Psychotic Drugs Update Project

FINAL 05-21 -2010

Detailed Abstraction Form

Article ID:_____ Reviewer:_____

First Author:_____
(Last Name Only)

Study Number:_____ of____ Description:_____
(Enter '1 of 1' if only one) (if more than one study)

1. Related Studies Flag: (ENTER 99 FOR NONE)
   ID numbers of articles that contributed data to this form:
   _____, _____, _____, _____, _____

2. Is the study design trial with crossover? (CIRCLE ONE)
   - Yes 1
   - No 2

3. Was the study described as randomized? (CIRCLE ONE)
   - Yes 1
   - No 2

4. Treatment Allocation
   a. Was the method of randomization adequate? (CIRCLE ONE)
   - Yes 1
   - No 2
   - Don't know 9

   b. Was the treatment allocation concealed? (CIRCLE ONE)
   - Yes 1
   - No 2
   - Don't know 9

5. Were groups similar at baseline regarding the most important prognostic indicators? (CIRCLE ONE)
   - Yes 1
   - No 2
   - Don't know 9

6. Is the study described as: (CIRCLE ONE)
   - Double blind 1
   - Single blind, patient 2
   - Single blind, outcome assessment 3
   - Single blind, not described 4
   - Open 5
   - Blinding not described 8
   - Not applicable 9

7. If reported, was the method of double blinding appropriate? (CIRCLE ONE)
   - Yes 1
   - No 2
   - Double blinding method not described 8
   - Not applicable 9

8. Was the outcome assessor blinded? (CIRCLE ONE)
   - Yes 1
   - No 2
   - Don't know 9

9. Was the care provider blinded? (CIRCLE ONE)
   - Yes 1
   - No 2
   - Don't know 9

10. Were patients blinded? (CIRCLE ONE)
   - Yes 1
   - No 2
   - Don't know 9

11 Drop-out rate questions: (CIRCLE ONE)
   a. Was the drop-out rate described and the reason given?
   - Yes 1
   - No 2
   - Don't know 9

   b. Was the drop-out rate acceptable? (CIRCLE ONE)
   - Yes 1
   - No 2
   - Don't know 9

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12. Were all randomized participants analyzed in the group to which they were originally assigned? (CIRCLE ONE)

Yes	1
No	2
Don't know	9

13. Other sources of potential bias:

a. Were co-interventions avoided or similar? (CIRCLE ONE)

Yes	1
No	2
Don't know	9

b. Was the compliance acceptable in all groups? (CIRCLE ONE)

Yes	1
No	2
Don't know	9

c. Was the outcome assessment timing similar in all groups? (CIRCLE ONE)

Yes	1
No	2
Don't know	9

14. What is the study trial name?

Enter code or 999 for no name:_____

15. What was the study's setting? (CHECK ALL THAT APPLY)

- ☐ Multi-center
- ☐ Single setting
- ☐ Community practice
- ☐ Long-term care facilities
- ☐ VA Healthcare System
- ☐ Other (enter code:_____)
- ☐ Setting not reported

16. What was the study's funding source? (CHECK ALL THAT APPLY)

- ☐ Government
- ☐ Hospital
- ☐ Industry
- ☐ Private (non-industry)
- ☐ Other (enter code:_____)
- ☐ Unclear
- ☐ Not reported

17. Did the article include a statement on the role of the funder? (CIRCLE ONE)

Yes	1
No	2

18. In what area was the study conducted? (CHECK ALL THAT APPLY)

- ☐ US
- ☐ Canada
- ☐ UK
- ☐ Western Europe
- ☐ Eastern Europe
- ☐ Australia/New Zealand
- ☐ Asia
- ☐ Middle East
- ☐ Latin America
- ☐ Other Country (spec:_____)
- ☐ Not reported

19. What was the percent of male participants?

(ENTER NUMBER OR 999)

___ ___ ___%

20. What was the racial/ethnic population studied?

(Check all that apply)

- ☐ Caucasian
- ☐ African Ancestry
- ☐ Hispanic
- ☐ Asian/Pacific Islander
- ☐ Native American
- ☐ Eskimo/Inuit
- ☐ Mixed
- ☐ Other-Not otherwise specified
- ☐ Not reported

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21. What were reported for the following questions regarding subjects' ages? (Enter number 999 for not reported)

Mean Age....._____

Median Age....._____

Age Range....._____ to _____

22. What were the study's inclusion criteria?

Text:_____

_____

_____

23. What were the study's exclusion criteria?

Text:_____

_____

_____

24. What were the comorbidities reported in the study?

(Check All That Apply)

- ☐ Anxiety
- ☐ Dementia/severe geriatric agitation
- ☐ Depression
- ☐ Insomnia
- ☐ Obsessive-compulsive disorder
- ☐ Personality disorders (DSM IV)
- ☐ PTSD
- ☐ Substance abuse
- ☐ Eating disorder (incl children 17 & under)
- ☐ ADHD (incl children 17 & under)
- ☐ Tourette's (incl children 17 & under)

Enter codes for others: _____, _____, _____,

_____, _____, _____, _____, _____,

____, _____, _____, _____, _____,

Units for Q25, Q26, Q27

1. Hour
2. Day
3. Week
4. Biweekly
5. Month
6. Year
7. Not described
8. Not Applicable
9. Not Reported
10. Min
11. Weekly
12. Monthly

25. Run-in period table: (Enter 998 if not described; enter 999 if no run-in.)

Length	Units	Placebo/Medication	How used for randomization?

26. Wash-out period table:
(Enter 998 if not described; enter 999 if no wash-out.)

Length	Units	Placebo/ Medication	How used for randomization?

27. Time of assessment: When were outcomes measured?
(Enter the number/code in the appropriate box, or circle YES/NO.)

Baseline?	YES / NO	
Follow-up	Number	Unit
1st		
2nd		
3rd		
4th		
5th		
6th		
7th		
8th		
Additional		

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28. Sample Size: (Enter N or 999 for not reported)

Screened: _____ Eligible: _____

Withdrawn:_____ Loss to follow-up: _____

29. What was the method of adverse events assessment?

(CHECK ALL THAT APPLY)

Monitored	☐
Elicited by investigator	☐
Reported spontaneously by patient	☐
Medical record	☐
Other (enter code: _____, _____, _____, _____)	☐
Not reported	☐
Not applicable	☐

30. Were stratified analysis reported on any of the following subgroups?

(CHECK ALL THAT APPLY)

Age	☐
Gender	☐
Race/Ethnicity	☐
Other (Specify: _____)	☐
None of the above	☐

31. Were patients class-naive?

(CIRCLE ONE)

Yes	1
No	2
Not reported	9

32. **OUTCOMES**: Please enter the outcomes measured and the final follow up time for each outcome measured.

a. Is everyone followed up at the same time?		b. If no, is the follow-up time reported as a mean?	
Yes	1	Yes	1
No	2	No	2

Units for Q32:

1. Hour	3. Week	5. Month	9. Not Reported
2. Day	4. Biweekly	6. Year	

Outcome	**Final Followup**	
Outcome text:	**Number**	**Unit**

INTERVENTIONS

33. Enter sample size and intervention data for each arm beginning with placebo or control, then in order of first mention.

Arm/Group	Sample size	Intervention		Dose	Units	Frequency	Dose Description	Duration of treatment	Units	Co-intervention(s)
1	_____ N ENTERING _____ N COMPLETING	Placebo ☐ Aripiprazole ☐ Asenapine ☐ Iloperidone ☐ Olanzapine ☐ Quetiapine ☐ Paliperidone ☐ Risperidone ☐ Ziprasidone ☐ Code: _____	_____	_____	_____	_____	_____	_____	_____	_____ _____ _____ _____ _____ _____
2	_____ N ENTERING _____ N COMPLETING	Aripiprazole ☐ Asenapine ☐ Iloperidone ☐ Olanzapine ☐ Quetiapine ☐ Paliperidone ☐ Risperidone ☐ Ziprasidone ☐ Code:_____	_____	_____	_____	_____	_____	_____	_____	_____ _____ _____ _____ _____ _____
3	_____ N ENTERING _____ N COMPLETING	Aripiprazole ☐ Asenapine ☐ Iloperidone ☐ Olanzapine ☐ Quetiapine ☐ Paliperidone ☐ Risperidone ☐ Ziprasidone ☐ Code:_____	_____	_____	_____	_____	_____	_____	_____	____ _____ _____ ____ _____ ____
	Enter a number for N entering and N completing or enter 999 if not reported	Check box for intervention or enter code(s) from list Put placebo in first arm		Enter # or range 998. Not Applicable 999. Not Reported	Enter a number 1. g 2. mg 3. tablets 4. Not Reported	Enter a number 1. Hour 2. Day 3. Week 4. Biweekly 5. Month 6. Year 9. NR	Enter a number 1. Fixed single dose 2. Fixed titration schedule 3. Flexible dose 4. Average final dose 9. Not Reported	Enter a number 997. Variable 998. Not Applicable 999. Not Reported	Enter a number 1. Hour 2. Day 3. Week 4. Biweekly 5. Month 6. Year 8. Not Applic. 9. NR	Enter code(s) or 998. Not Applicable 999. Not Reported

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Interventions (continued)

Enter sample size and intervention/exposure data for each arm beginning with placebo or control, then in order of first mention.

Arm/Group	Sample size	Intervention	Dose	Units	Frequency	Dose Description	Duration of treatment	Units	Co-intervention(s)
4	_____ N ENTERING _____ N COMPLETING	Aripiprazole ☐ Asenapine ☐ Iloperidone ☐ Olanzapine ☐ Quetiapine ☐ Paliperidone ☐ Risperidone ☐ Ziprasidone ☐ Code:_____	_____	_____	_____	_____	_____	_____	_____ _____ _____ _____ _____ _____
5	_____ N ENTERING _____ N COMPLETING	Aripiprazole ☐ Asenapine ☐ Iloperidone ☐ Olanzapine ☐ Quetiapine ☐ Paliperidone ☐ Risperidone ☐ Ziprasidone ☐ Code:_____	_____	_____	_____	_____	_____	_____	_____ _____ _____ _____ _____ _____
6	_____ N ENTERING _____ N COMPLETING	Aripiprazole ☐ Asenapine ☐ Iloperidone ☐ Olanzapine ☐ Quetiapine ☐ Paliperidone ☐ Risperidone ☐ Ziprasidone ☐ Code:_____	_____	_____	_____	_____	_____	_____	_____ _____ _____ _____ _____ _____
	Enter a number for N entering and N completing or enter 999 if not reported.	Check box for intervention or enter code(s) from list. Put placebo in first arm	Enter # or range 998. Not Applicable 999. Not Reported	Enter a number 1. g 2. mg 3. tablets 9. Not Reported	Enter a number 1. Hour 2. Day 3. Week 4. Biweekly 5. Month 6. Year 9. NR	Enter a number 1. Fixed single dose 2. Fixed titration schedule 3. Flexible dose 4. Average final dose 9. Not Reported	Enter a number 997. Variable 998. Not Applicable 999. Not Reported	Enter a number 1. Hour 2. Day 3. Week 4. Biweekly 5. Month 6. Year 8. Not Applic. 9. NR	Enter code(s) or 998. Not Applicable 999. Not Reported

Note: If there are more than six arms to the study, please print another page for adding arms 7, 8, 9, etc.