

Newer Drugs for Insomnia

Key Questions

1. What is the comparative effectiveness of Newer Drugs for Insomnia in treating patients with insomnia?
2. What is the comparative tolerability and safety of Newer Drugs for Insomnia when used to treat patients with insomnia?
3. Are there subgroups of patients for which one Newer Drug for Insomnia is more effective or associated with fewer adverse events based on demographics (age, racial groups, and gender), other medications (e.g., stimulants), co-morbidities (including obstructive sleep apnea, other mental disorders), pregnancy, or history of substance abuse?

Inclusion Criteria

Population:

Adults and children with insomnia, including (DSM-IV-TR diagnoses):

- Primary insomnia
- Breathing-related sleep disorder (e.g., obstructive sleep apnea)
- Insomnia related to another mental disorder
- Substance-induced sleep disorder, insomnia type
- Sleep disorder due to a general medical condition, insomnia type
- Wherever possible, data on duration of therapy (time to tolerance) will be evaluated within the context of comparative effectiveness.

Interventions

Zaleplon (Sonata[®])
Zolpidem (Ambien[®])
Zolpidem extended release (Ambien CR[®])
Eszopiclone (Lunesta[®])
Ramelteon (Rozerem[®])
Zopiclone (Imovane[®], Canada only)

Effectiveness outcomes

Sleep latency
Sleep duration
Number of awakenings
Sleep quality
Wake time after sleep onset
Daytime alertness
Tolerance
Rebound

Safety outcomes

Overall adverse effect reports, withdrawals due to adverse effects, serious adverse events, specific adverse events including, but not limited to: abuse potential, withdrawal symptoms, dependency, and impairment of memory/daytime functioning

Study designs

Effectiveness:

- Controlled clinical trials of an included drug versus placebo or versus any active comparator (including, but not limited to, another included drug, benzodiazepines, trazodone, diphenhydramine, and amitriptyline).
- Good-quality systematic reviews

Adverse Events (dependency and withdrawal symptoms):

- Controlled clinical trials
- Observational studies (case-control, case series, case reports, cohort studies, surveys).