



DFASM1 Free Ride - Gas supply

Placebo-controlled trial of agomelatine in the treatment of major depressive disorder

<https://pdfs.semanticscholar.org/8a46/e77caa36e0ee9225d4ea3063681c65cc63c0.pdf>

Lecture rapide préparatoire : Proposition de corrigé

• Scanning

- Aim of the study → Last paragraph of Introduction *In view of the currently available information, the purpose of this placebo-controlled flexible-dosing study was to confirm the efficacy and safety of agomelatine 25–50 mg/day in patients who met criteria for a current episode of MDD (MDE).*

▪ What this study suggests → Beginning & end of Discussion → Significantly more effective than placebo, effective in moderate & severe depression, high tolerability....

▪ Limitations to this study acknowledged by authors: → End of Discussion →

None

• Skimming

▪ Introduction

- Antidepressants in MDD
- Selective serotonin re-uptake inhibitors
- Need for alternative & improved antidepressants
- Purpose of study

▪ Experimental procedures

- Study design
- Patients
- Assessment of efficacy
- Statistical analyses
- Safety & tolerability

▪ Results

- Patient disposition & characteristics
- Efficacy in full ITT population
 - Primary outcomes
 - Secondary outcomes: response, time to first response, remission
 - Secondary outcome: CGI analysis
- Efficacy in ‘severe’ subpopulation
 - Primary outcome
 - Secondary outcomes: response, time to first response, remission
 - Secondary outcome: CGI analysis
- Tolerability & safety

▪ Discussion

- Agomelatine more effective than placebo
- As effective as currently available antidepressants
- Superior rate of responders to agomelatine in severe subpopulation of depressed patients
- Early response in ‘severe’ subpopulation
- Significant benefit from dose increase to 50 mg/day
- Bias limitation
- High tolerability & low drop-out rates
- Conclusion: significant efficacy, early onset of action, safety & tolerability, low discontinuation rate & dosage flexibility

• Connaissances en Statistiques : rafraîchissez-les ! Assurez-vous que vous savez exactement ce que l'on entend par :

- HAM-D score
- CGI-severity & CGI-Improvement scores
- ITT population

- *LOCF method*
- *Two-sided Student's t test*
- *Covariance*
- *Chi-square test*
- *Logistic regression model*
- *Log-rank test*
- *Mean age +/- S.D*
- *Median*
- *Baseline*
- *Endpoint*

- **Chaînes de noms**

- ***This randomized, double-blind, placebo-controlled, parallel-group, international multicentre study...***

→ Le nom est le dernier élément, ***study***

- ***The 17-item Hamilton Rating Scale***

→ Tout ce qui est entre l'article ***The*** et le nom ***Scale*** fonctionne comme un adjectif, donc est **invariable (17-item)**

- **Phrases longues** : repérez le **verbe principal**, tout ce qui est avant ce verbe est le groupe sujet. Trouvez le **nom principal** dans le groupe sujet. S'il y a des parenthèses, **laissez glisser les yeux sans vous y arrêter**, vous reviendrez sur l'information lorsque vous aurez repéré le verbe et le sujet. Le sens se mettra plus facilement en place.

- ***This variability in treatment effectiveness may be influenced by patient heterogeneity involving genetic, metabolic, personality, environmental and age differences (Kirchheiner et al., 2003; Meyer et al., 1996; Joyce et al., 2003) as well as treatment variables including drug selection, dose and treatment duration***

- **Pronoms personnels, possessifs & démonstratifs** : trouvez le **référent** (le nom auquel le pronom renvoie) :

- ***Patients with other types of depression or psychiatric conditions (including bipolar I and II or dysthymic disorders) and those who displayed marked suicidal intent...***

