Thank you. I'll try to be a little fast and try to finish within five minutes if I could.
So, meta zepin plus granisetron and exomethosone for carboplatin induced CA and V in a patient's
with thoracic cancer, a prospective multi-center phase two. So, first of all, why do we need
to do this study? And we already have one more drug in this space, so, lansapine. At
the end, we try to discuss if at all, if time permits, what's the difference between
allansapine and mirtazepine and is there any scope for mirtazepine per se? This is
the abstract I'm going to present. I'll try to go through it. So, basically, mirtazepine
blocks as everyone knows phi H2O and 2C, phi H3 and histamine similar to the tapholansapine.
The main problem with the allansapine is with respect to the quality of life, weight gain
and somnalescence and dry mouth. Then, they tried addressing this allansapine induced side
effects. Can we replace it with the other group who has got relatively same efficacy
with lesser side effects? This study aimed at investigating the efficacy and safety of
mirtazepine in a triple combination therapy along with granisetron and exa for a patient's
especially who are treated with a carboplatin of AUC more than four in a lung cancer patients.
It's a prospect to open label study with a phase two involving four centers in Japan.
Patients were moderately to highly amitogenic chemotherapy naive. They should receive at
least carboplatin of AUC more than four and the mirtazepine dose used was 15 mg per day
orally but at bedtime of day two to day five. Inclusion criteria, 20 to 80 years, good
e-cock performance status. Previously, they shouldn't receive a MSC or HCC chemotherapy
regimen and they shouldn't have a brain mitz or a carcinomatosis. Inclusion criteria
being the enzyme function should be normal, STG LT should be less than 100, bilibin should
be normal, have got a good creatin clearance of more than 40 and shouldn't have any drugs
which causes interaction with these abo mentioned drugs or CIP-34 inhibitors or HIV proteins
inhibitors and lithium. Exclusion criteria being hypersensitivity of any of the three
drugs which are being used under treatment with anti-ematics at the time of enrollment
and they shouldn't have an opioid for supportive care because opioid per second cause nausea
as we know because one of the criteria is to have a complete CR of early and delayed
nausea and they shouldn't have other comorbid conditions like unstable angina, ischemic
heart disease, diode, nal ulcer or they shouldn't be habitual smokers. Treatment regimen is
granted to 1 mg, IV 30 minutes before chemotherapy on day one. Dexa either it could be an IV

or an oral if it is an IV 10 mg if it is an oral to LMG 30 minutes prior to the chemo
on day one and on days to day three your dose is reduced into a 8 in IV 6 in oral. We are giving mirtas a 15 mg oral at bed time for four consecutive days from initial
administration of carboplatin based regimens especially when you are using the carboplatin
along with the paklitaxil as a combination which we use for majority of the times the
dose of dexast to be increased to 20 mg IV or 20 mg oral on day one to prevent the prevention infusion related hypersensitivity as well though it has a anti-ematic activity
as well. So, if you are using a carbo alone it is 10 mg IV or 12 mg oral if you are using paklitaxil plus carbo it is 20 mg. How did they assess the patients? Patients demographic
and medical data was recorded in diaries and patients were asked to maintain a record
of nausea, vomiting whatever they do have from 24 hours from the initiation of carboplatin
to 5 days that is 120 hours in which they report the presence or options of nausea decreased
appetite and the side effects like somnalescence and decreased concentration on a 4 point liquid
scale 0 to severe 0 being none one is mild two is moderate four is severe. Vomiting was
reported on five times scales than 1 to 2, 3 to 5 and 6 times more use of rescue medication
using a four times scale similar to that of abograding. Overall after the assessment around
0 to 120 hours that is five days patient reported study diaries were collected patients were
assessed before the initiation of chemotherapy and at the end of five days overall patient
satisfaction with anti-ematic therapy was measured on a seven point likert scale very
satisfied being high and very dissatisfied being 0. The primary outcomes of this study
are CR rate in the delayed period meaning by definition there should not be emetic episodes
and they should not require the usage of a rescue medication for CA envy up to five days
after the initiation of carboplatin based regimen. Second trend points being CR at the end of
five years CR at the five days and CR at the end of 24 hours. Complete control is defined
as I previously said no emetic episodes no nausea and no usage of rescue medication
both in acute and delayed period. Total control rate meaning no emetic episodes and no use
of rescue medication and no nausea both in acute and delayed period and patient related outcomes
were calculated on CTCE, ProCT version one and side effects on version five.
Statistical analysis this study hypothesizely said that CR rate of the CR for 15 mg mita
amrita zapin when combined with granisate and dexase based regimen would be statistically
significant for CR rates for doublet like for example if you consider granisate and dexase
and you add the third drug at least there should be more than 15 percent improvement

in the CR rate which could be clinically meaningful and as we know from the other trials the CR
rates for a delayed CA and V monitoring was around up to two and off around 68 you have
to remember these two figures either if it is incremental value of more than 15 or if
the CR rates are more than 68 then for all practical purposes we are through this mita zapin.
Assuming the CR rate of around 69 and the null hypothesis and 84 under the alternate hypothesis
we need at least 46 plus 46 patients which are it is time up no 46 patients were required
to achieve a power of 80 and one sided alpha significance of 0.1 and to for this study
to conduct we need at least 51 patients this is a flow cons or flow diagram patient demographics
so if you see the results the efficacy that mita zapin containing therapy if you give
a triplet of mita zapin granisate and dexase showed a delayed CR of 83 percent which we
anticipated if it is more than 68 we are fine but in this study which is 83 and if you see
the CR rates in both acute and overall period it is 100 percent and 83 percent acute period
it is 100 and overall it is 83 if you see the complete rate or complete control rate also
it is 83 and 72 percent respectively if you see whenever you give a carbobulate and base
regimen the maximum amount of nausea vomiting would be on day 3 to day 5 because the day
1 and day 2 would be taken care by your granisate and dexase but day 3 to day 5 is what which
trouble you that is the reason why we use the other nk1 receptor in this space so if you see safety
and if you see with this regimen even at the end of day 5 83 percent of the patient doesn't
have an vomiting episode or does not require a rescue medication though if it is more than 68
positive point if you see the safety aspects very less only one patient had that is 2 percent of
the patient had a grade 3 dry mouth except for that there is no grade 3 or above events this is
one of the important points why do you want to consider this in a phase 3 when compared to the
olein zapin where the grade 3 events are more than 5 percent and the same has been explained
here again grade 3 dry mouth was seen only in 1 percent and if you see the patient reported
outcome but they are much better when compared to the other drugs of same group only one patient
had a severe dry mouth and two patient had a constipation the same has been repeated once again
to conclude the administration of 15 mg of mitasapin combined with granisectant
dexase shows a promising activity along with manageable safety that is only one patient had
a grade 3 this one these findings suggest that it could be one of the reasonable choices for
thoracic cancers especially if you are using a carbopleton based regimen where the delayed

emissis is high that is day 3 to day 5 though it is a it has got some limitations it's a single
institution study with four centers only a thoracic cancers have been included into it but a further
investigation is warranted to compare the efficacy of mitasapin to a triplet standard like aprypitant
or nk1 which is already into a guidelines thank you for your patient hearing great