



#### Oral Arsenic and Retinoic Acid for High-Risk Acute Promyelocytic Leukemia

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# Home-based treatment is an ideal model for Cancer



# Home-based treatment is an ideal model for APL

JOURNAL OF CLINICAL ONCOLOGY

ONCOLOGY GRAND ROUNDS

#### Postremission Therapy in Acute Promyelocytic Leukemia: Room for Improvement?

Jeffrey E. Lancet, H. Lee Moffitt Cancer Center, Tampa, FL

See accompanying article doi: 10.1200/JCO.2013.53.3570

#### The NEW ENGLAND JOURNAL of MEDICINE

**Outpatient Oral Treatment for Acute Promyelocytic Leukemia** 

TO THE EDITOR: Zhu and Huang (Dec. 4 issue)<sup>1</sup> regarded as a rapidly fatal disease, APL is now report excellent, though preliminary, outcome curable in most cases with the use of targeted results in 20 patients with non-high-risk acute treatment alone and without chemotherapy.<sup>2</sup> promyelocytic leukemia (APL) treated with oral However, population-based studies of APL have arsenic and all-trans retinoic acid (ATRA) in a shown rates of early death of up to 29% in devel-"largely home-based treatment protocol." Once oped countries such as Sweden and the United

N ENGLJ MED 372;9 NEJM.ORG FEBRUARY 26, 2015 The New England Journal of Medicine

#### **Clinical Cancer** Research



Amer M Zeidan and Steven D Gore

Clin Cancer Res 2014;20:4985-4993.



**Review Article** 

The evolution of arsenic in the treatment of acute promyelocytic leukemia and other myeloid neoplasms: Moving toward an effective oral, outpatient therapy

Lorenzo Falchi MD. Srdan Verstovsek MD. PhD. Farhad Ravandi-Kashani MD. Hagop M. Kantarjian MD 🗠

AAR

# ATRA+ATO without Chemo for non-high-risk APL



Lo-Coco F, et al. N Engl J Med 2013; 369:111

Platzbecker U, et al. JCO 35:605

#### Home-based treatment become reality in non-high-risk APL (Beijing Protocol)



#### Compared study between RIF+ATRA and ATO+ATRA in non-high-risk APL





# Attempts at minimizing chemotherapy have proven feasible in high-risk APL



Iland H, et al. Lancet Oncol 2015; 2:e357

Burnett AK, et al. Lancet Oncol 2015;16:1295

#### Question

• Whether our Beijing Protocol in non-highrisk APL also benefit for high-risk patients

#### **Purpose and Protocol**

• To evaluate the efficacy and safety of oral arsenic and ATRA for high-risk APL patients.



oral tetra-arsenic tetra-sulphide formula (Realgar-Indigo naturalis formula, RIF)

# Inclusion criteria

- Newly diagnosis of de novo APL
- 16 -65 years old;
- WBC  $\geq 10 \times 10^9$ /L before treatment ;
- Adequate hepatic and renal reserve
- Performance Status (PS) score 0-2(WHO);
- provide written informed consent.

# Endpoints

• Primary endpoint:

Complete molecular remission (CMR) rate at 6 months

Secondary endpoints:
CR; EFS; Safety;
Hospitalized days; Medical costs

#### Results

- Enrollment time: 2014.4-2016.9
- Numbers of patients: 20

### **Characteristics of 20 Patients**

Characteristic	Value
Age — yr	35.5 (16-61)
Male sex -no. (%)	9(45)
WBC (×10 <sup>9</sup> /L)	32.9 (10.6-140.8)
PLT (×10 <sup>9</sup> /L)	32.5 (5-74)
Blasts of BM (%)	90 (34-97.5)
PML-RARA/ABL (%)	37.6 (20.1-92.4)
Type of transcript (L/S/V)	10/7/3
Cytogenetics-no.(%)	
solo t(15;17)	15(75)
others	5 (25)
Fibrinogen	163 (60-429)
D-dimer	9296 (2570- >20000)

#### Hematological and molecular remission



15



## **WBC** kinetics during induction





### Liver damage during induction



19

#### Hospital days during whole treatment course



20

#### Conclusions

- Oral arsenic and ATRA, with minimal cytoreductive chemo during induction, proved to be effective, safety, convenient.
- Employed an outpatient post-remission treatment protocol is feasible and needs to be confirmed in more high-risk APL patients

# Acknowledgements

- All the patients involved in this study
- My colleagues
- Prof. Lo-Coco F







# Thanks for your attention